

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
2 August 2001 (02.08.2001)

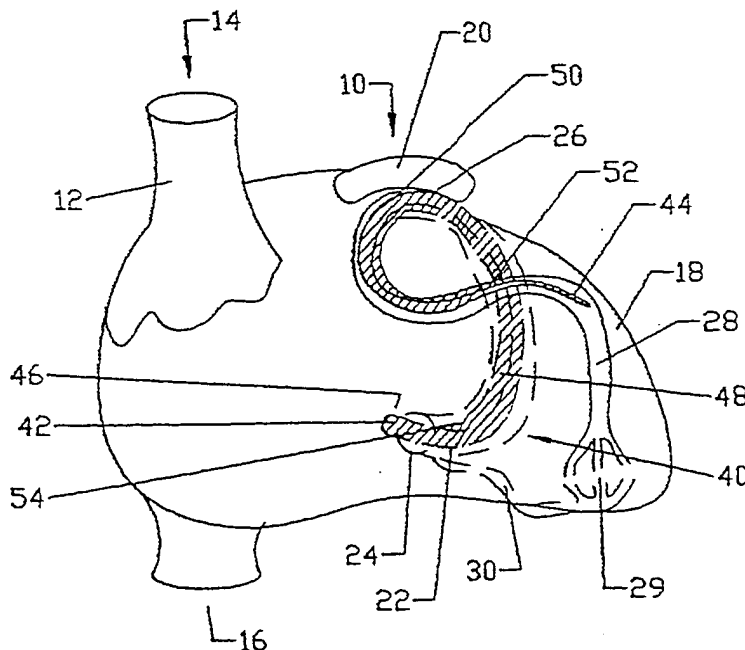
PCT

(10) International Publication Number  
WO 01/54618 A1

- (51) International Patent Classification<sup>7</sup>: A61F 2/02
- (21) International Application Number: PCT/US01/02823
- (22) International Filing Date: 29 January 2001 (29.01.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
09/494,233 31 January 2000 (31.01.2000) US
- (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:  
US Filed on Not furnished (CIP)  
Not furnished
- (71) Applicant (for all designated States except US): MITRALIFE [US/US]; 355 Tesconi Circle, Santa Rosa, CA 95401 (US).
- (72) Inventors; and  
(75) Inventors/Applicants (for US only): LANGBERG, Jonathan, J. [US/US]; 1088 Clifton Road, Atlanta, GA 30307 (US). LESH, Michael, D. [US/US]; 301 Monte Vista Avenue, Mill Valley, CA 94941 (US). VAN DER BERG, Eric [US/US]; 587 Dawn Drive, Sunnyvale, CA 94087 (US).
- (74) Agent: KLEIN, Richard, L.; MiraLife, 355 Tesconi Circle, Santa Rosa, CA 95401 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,

[Continued on next page]

(54) Title: PERCUTANEOUS MITRAL ANNULOPLASTY AND CARDIAC REINFORCEMENT



(57) Abstract: A mitral annuloplasty and left ventricle restriction device (40, 100) is designed to be transvenously advanced and deployed within the coronary sinus (22) and in some embodiments other coronary veins (28, 30). The device places tension on adjacent structures, reducing the diameter and/or limiting expansion of the mitral annulus and/or limiting diastolic expansion of the left ventricle. These effects may be beneficial for patients with dilated cardiomyopathy.

WO 01/54618 A1

IDS  
Took delivery?



IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**Published:**

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

## PERCUTANEOUS MITRAL ANNULOPLASTY AND CARDIAC REINFORCEMENT

5 The present invention relates to intravascular prostheses for remodeling an  
extravascular anatomical structure. In one application, the present invention relates to a  
mitral annuloplasty and cardiac reinforcement device which is transluminally  
implantable in the coronary sinus.

### Background of the Invention

10 Dilated cardiomyopathy occurs as a consequence of many different disease  
processes that impair myocardial function, such as coronary artery disease and  
hypertension. The left ventricle enlarges and the ejection fraction is reduced. The  
resulting increase in pulmonary venous pressure and reduction in cardiac output cause  
congestive heart failure. Enlargement of the mitral annulus and left ventricular cavity  
15 produce mitral valvular insufficiency. This in turn, causes volume overload that  
exacerbates the myopathy, leading to a vicious cycle of progressive enlargement and  
worsening mitral regurgitation.

According to recent estimates, more than 79,000 patients are diagnosed with  
aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral  
valve or aortic valve replacement procedures are performed annually in the U.S., along  
20 with a significant number of heart valve repair procedures.

Various surgical techniques have been developed to repair a diseased or  
damaged valve. One repair technique which has been shown to be effective in treating  
incompetence, particularly of the mitral and tricuspid valves, is annuloplasty, in which  
the effective size of the valve annulus is contracted by attaching a prosthetic  
25 annuloplasty ring to the endocardial surface of the heart around the valve annulus. The  
annuloplasty ring comprises an inner substrate of a metal such as stainless steel or  
titanium, or a flexible material such as silicone rubber or Dacron cordage, covered with  
a biocompatible fabric or cloth to allow the ring to be sutured to the heart tissue. The  
annuloplasty ring may be stiff or flexible, may be split or continuous, and may have a  
30 variety of shapes, including circular, D-shaped, C-shaped, or kidney-shaped. Examples  
are seen in U.S. Pat. Nos. 4,917,698, 5,061,277, 5,290,300, 5,350,420, 5,104,407,  
5,064,431, 5,201,880, and 5,041,130, which are incorporated herein by reference.

Annuloplasty rings may also be utilized in combination with other repair techniques such as resection, in which a portion of a valve leaflet is excised, the remaining portions of the leaflet are sewn back together, and a prosthetic annuloplasty ring is then attached to the valve annulus to maintain the contracted size of the valve.

5 Other valve repair techniques in current use include commissurotomy (cutting the valve commissures to separate fused valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of the valve leaflets or annulus. Annuloplasty rings may be used in conjunction with any repair procedures where  
10 contracting or stabilizing the valve annulus might be desirable.

Although mitral valve repair and replacement can successfully treat many patients with mitral valvular insufficiency, techniques currently in use are attended by significant morbidity and mortality. Most valve repair and replacement procedures require a thoracotomy, usually in the form of a median sternotomy, to gain access into  
15 the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing the two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents. Alternatively, a thoracotomy may be performed on a lateral side  
20 of the chest, wherein a large incision is made generally parallel to the ribs, and the ribs are spread apart and/or removed in the region of the incision to create a large enough opening to facilitate the surgery.

Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of  
25 cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta to occlude the aortic lumen between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the ascending aorta, to arrest cardiac function.  
30 The patient is placed on extracorporeal cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

Of particular interest in the present application are techniques for the repair and replacement of the mitral valve. The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into an anterior position. An opening, or atriotomy, is then made in the right side of the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve adjacent to the atriotomy. One of the previously identified techniques may then be used to repair or replace the valve.

An alternative technique for mitral valve access has been used when a median sternotomy and/or rotational manipulation of the heart are inappropriate. In this technique, a thoracotomy is made in the right lateral side of the chest, usually in the region of the fourth or fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for cannulation of the aorta and/or coronary arteries to induce cardioplegia, manipulation of surgical instruments, removal of excised tissue, and introduction of an annuloplasty ring or a replacement valve through the atriotomy for attachment within the heart.

Mitral valve surgery, including mitral annuloplasty, is usually applied to patients with intrinsic disease of the mitral apparatus. As described above, these patients may have scarring, retraction, tears or fusion of valve leaflets as well as disorders of the subvalvular apparatus. Definitive repair requires direct visualization of the valve.

Patients who develop mitral regurgitation as a result of dilated cardiomyopathy do not have intrinsic mitral valve disease. Regurgitation occurs as the result of the leaflets being moved back from each other by the dilated annulus. The ventricle

enlarges and becomes spherical, pulling the papillary muscles and chordae away from the plane of the valve and further enlarging the regurgitant orifice. In these patients, correction of the regurgitation does not require repair of the valve leaflets themselves, but simply a reduction in the size of the annulus and the sphericity of the left ventricle.

5 Mitral annuloplasty without repair of the leaflets or chordae has been shown to be effective in patients with dilated cardiomyopathy who are refractory to conventional medical therapy. Bolling and coworkers have operated on a cohort of such patients with New York Heart Association Class III and IV symptoms. Average symptom severity decreased from 3.9 preoperatively to 2.0 after surgery. Hemodynamics and  
10 ejection fraction improved significantly. Other investigators have achieved similar results as well. However, the morbidity, risks and expense of surgical annuloplasty are very high in patients with cardiomyopathy and congestive heart failure. Thus, a variety of new techniques for the treatment of congestive heart failure are being explored as adjuncts to drug therapy.

15 Several cardiac restraint devices have been described. U.S. Patent No. 5,702,343 to Alferness discloses a cardiac reinforcement device that is applied as a jacket over the epicardium in order to limit diastolic expansion. However, this requires an open chest operation to implant and does not directly affect the diameter of the mitral annulus. Another approach is disclosed in U.S. Patent No. 5,961,440 to Schweich, et al., in  
20 which tension members are placed through opposite walls of the heart such that they span the ventricle. Less invasive and "minimally" invasive techniques for valve repair and replacement continue to evolve, both on a stopped heart and on a beating heart. These techniques may provide some benefits over open chest procedures, but they are still attended by significant morbidity and mortality risks.

25 A need therefore remains for methods and devices for treating mitral valvular insufficiency, which are attended by significantly lower morbidity and mortality rates than are the current techniques, and therefore would be well suited to treat patients with dilated cardiomyopathy. Optimally, the procedure can be accomplished through a percutaneous, transluminal approach, using simple, implantable devices which do not  
30 depend upon prosthetic valve leaflets or other moving parts.

Summary of the Invention

The invention according to one mode is a medical system with a medical device for remodeling a tissue structure adjacent to a body space that is defined at least in part by a tissue wall in a patient. The medical device has a prosthesis that in a first configuration having a first shape is adapted to be delivered into and positioned at least in part within the body space. The prosthesis is thereafter adjustable within the body space to a second configuration having a second shape that is adapted at least in part to exert a force from within the body space onto the adjacent tissue structure in order to remodel the adjacent tissue structure.

According to one beneficial mode of this aspect wherein the adjacent tissue structure has a wall that circumscribes a space having a diameter, the prosthesis when adjusted from the first configuration to the second configuration within the body space is adapted to compress the adjacent tissue structure to thereby reduce its diameter.

The invention according to another aspect is a medical system with a medical device for remodeling an extravascular tissue structure adjacent to a vessel in a patient. The device has a prosthesis that in a first configuration having a first shape is adapted to be delivered into and positioned at least in part within the vessel. The prosthesis is thereafter adjustable within the vessel to a second configuration having a second shape and is adapted to thus exert a force from within the vessel onto the extravascular tissue structure in order to remodel the extravascular tissue structure.

The invention according to another aspect is a medical system with a medical device for remodeling a mitral valve annulus from within a coronary sinus in a patient. The prosthesis is adapted to be positioned in the first configuration at least in part within a coronary sinus and is adapted to remodel a mitral valve annulus adjacent to the coronary sinus when the prosthesis is located at least in part within the coronary sinus and is adjusted to the second configuration. This aspect is particularly beneficial for use in performing mitral valve annuloplasty and treating mitral valve insufficiency.

According to one highly beneficial mode for these various system aspects of the invention just provided, the prosthesis is an elongate body that extends between proximal and distal ends.

The following are further beneficial embodiments and related applications for this mode with respect to a an elongate body for use according to the aspect of the



mitral valve remodeling aspect of the invention. Such further embodiments are also generally considered to be beneficially applicable to the other medical system aspects just described for the invention with respect to the prostheses constructed for remodeling operation generally from within a body space or more specifically from within a vessel, respectively, and in particular without limitation with respect to the mode wherein the respective prosthesis is an elongate body. The following embodiments and applications are considered to be independently beneficial, and are not generally considered mutually exclusive or reliant unless expressly described as such.

In one such further embodiment, the elongate body is adapted to be permanently implanted in the patient at least in part within the coronary sinus in the second configuration in order to provide chronic remodeling of the mitral valve annulus.

In another further embodiment, the device further includes a guidewire tracking member such as a guidewire lumen that is adapted to track over a guide wire in order to position the elongate body within the coronary sinus.

According to another further embodiment, the elongate body is selectively adjustable between the first and second configurations while the elongate body is located at least in part within the coronary sinus. The elongate body is adapted to be temporarily implanted at least in part within the coronary sinus in the second configuration for temporary remodeling of the mitral valve annulus and to be thereafter removed from the coronary sinus in the first configuration.

In still another further embodiment, the elongate body within the coronary sinus comprises a substantially similar length between the first and second configurations.

In still another further embodiment, the elongate body within the coronary sinus is relatively non-expandable while the elongate body is adjusted between the first and second configurations. In another further embodiment, the elongate body within the coronary sinus is relatively non-compressible while the elongate body is adjusted between the first and second configurations.

According to a further embodiment, the elongate body has a length between its respective proximal and distal ends that is less than about 10 cm.

In yet a further embodiment, the device further includes a lock for retaining the elongate body in the second configuration at least in part within the coronary sinus.

In yet a further embodiment, in the second configuration the second shape for the elongate body at least within the coronary sinus defines an arc.

5 In a further embodiment, the device further includes an anchor for retaining the elongate body at least in part within the coronary sinus. In one application, the anchor is provided at a region along a distal portion of the elongate body. In another application, the anchor provides a friction enhancing surface for engaging a wall of the coronary sinus. In another application, the anchor may have at least one barb for piercing a wall of the coronary sinus.

10 In further applications of the anchor embodiment, the anchor may be provided at the proximal or distal end of the elongate body, or multiple anchors may be provided. One such application provides a proximal anchor that is adapted to be positioned outside of the coronary sinus and against a wall of the right atrium in order to anchor the elongate body at least in part within the coronary sinus. Another such application is a distal anchor that is adapted to be positioned within the great cardiac vein when the  
15 elongate body is located at least in part within the coronary sinus.

In still a further embodiment, a forming element is secured to the elongate body at a point of attachment and that is moveable relative to the elongate body in order to adjust the elongate body within the coronary sinus between the first and second configurations.

20 In one highly beneficial application of this embodiment, the forming element between the point of attachment and the proximal end of the elongate body is substantially circumferentially confined by the elongate body. This may be achieved in a further beneficial example by providing the forming element within a substantially tubular wall or other radially confining housing of the elongate body.

25 In another highly beneficial application, the forming element has a proximal extension that extends proximally from the elongate body and externally of the patient when the elongate body is located at least in part within the coronary sinus, and the elongate body within the coronary sinus is adjustable within the coronary sinus from the first configuration to the second configuration by manipulating the proximal extension  
30 outside of the patient.

In another application wherein an anchor is provided for retaining at least a portion of elongate body within the coronary sinus, and the axial length of the elongate

body between the anchor and the point of attachment of the forming element to the elongate body is within the range of from about 2 cm to about 8 cm. In still another application, an annuloplasty zone is provided on a proximal portion of the body that is adapted to be positioned within the coronary sinus for annuloplasty via the coronary sinus, and an anchor zone is provided on a distal portion of the body. The forming element is attached to the body between a mid-point of the annuloplasty zone and a mid-point of the anchor zone, such that force imparted from the forming element at the point of attachment with respect to the proximal end of the body deflects at least a portion of the annuloplasty zone into an arcuate configuration.

In still another particularly beneficial application of the forming element embodiment, the elongate body is adjustable from the first configuration to the second configuration principally by applying a force from the forming element to the elongate body.

In one more detailed application, wherein the elongate body is adjustable from the first configuration to the second configuration principally by transmitting an axial force from the forming element onto the elongate body relative to the longitudinal axis of the embodiment. In still further detail to this application, the elongate body may be adjustable from the first configuration to the second configuration in response to proximal retraction of the forming element. In another regard, the elongate body may be movable from the first configuration to the second configuration in response to distal advancement of the forming element. In the alternative or in addition to these axial force applications, the forming element may be adapted to adjust the elongate body from the first configuration to the second configuration at least in part by providing a rotational force along at least a portion of the forming element. In one regard, the forming element according to this rotational application may include a rotational force transmission member coupled to an axial force transmission member via a rotational coupler such that rotational forces are converted to axial forces to deflect the elongate body.

In a particularly beneficial further application of the forming element embodiment, the elongate body is adapted to be uncoupled in the second configuration from at least a portion of the forming element as a permanent implant located at least in part within at least the coronary sinus. This may be accomplished by adapting the

forming element to be severed while the elongate body is positioned at least in part within the coronary sinus in the second configuration. In one regard, a cutting tool may be provided that is adapted to cut the forming element while the elongate body is positioned at least in part within the coronary sinus. In another regard, the forming element includes proximal and distal members that are detachably engaged in a manner that allows for force transmission from outside the body of the patient to an attachment point to the elongate body, and also for the members to be uncoupled to leave the elongate body and distal member within the patient as a device implant.

In another particularly beneficial further application of the forming element embodiment, the medical device further includes a lock that is adjustable between disengaged and engaged configurations. The disengaged configuration allows the forming element to be moveable relative to the elongate body in order to adjust the elongate body from the first configuration to the second configuration at least in part within the coronary sinus. The engaged configuration engages the forming element to substantially fix the forming element relative to the elongate body when the elongate body is in the second configuration at least in part within the coronary sinus. In a particular application that is highly beneficial for selective adjustment of the elongate body between first and second configurations, the lock is selectively adjustable between the engaged and disengaged configurations. In another beneficial application, locking and/or unlocking tools may also be provided in order to adjust the lock from the disengaged configuration to the engaged configuration, or visa versa, respectively.

In another further beneficial embodiment of the medical system aspect of the invention, a deployment system is provided that cooperates with the elongate body in order to deliver the elongate body or prosthesis in the respective first configuration and shape to the desired location for subsequent operation for tissue remodeling. In one particularly beneficial further detailed embodiment, the deployment system includes at least in part a delivery member that is coupled to the elongate body or prosthesis and is adapted to advance the elongate body or prosthesis into the coronary sinus.

The invention according to another aspect is a method for providing a medical device for use in treating a patient from within a vein that is associated with the patient's heart. The method according to this aspect includes providing an array of medical devices, each having a prosthesis or elongate body that is adjustable in-situ

from a first configuration having a first shape to a second configuration having a second shape. Each elongate body of each medical device of the array is constructed to have a unique size relative to the elongate bodies of the other medical devices of the array. This method aspect also includes choosing the medical device from the array at least in part based upon a known measurement for a vein that is associated with the patient's heart. A comparison between the measurement of the vein with the unique size for the elongate body of the chosen medical device provides indicia that the unique size is appropriate for being delivered in the first configuration into the patient's respective vein and for being adjustable within the vein from the first configuration to the second configuration in order to remodel the mitral valve annulus from within the vein.

According to one mode of this aspect, the medical device is chosen at least in part based upon a known measurement for a coronary sinus. According to another mode wherein the vein has a central axis, the known measurement comprises at least one of: a length of at least a portion of the vein, a radius of curvature of the vein along the central axis, and a diameter of the vein across the central axis.

This aspect may be further modified according to another aspect of the invention to include providing the array of devices such that each device is constructed to have at least one unique geometry relative to the elongate bodies of the other medical devices. This method aspect further includes choosing the medical device from the array at least in part based upon a known measurement for a parameter associated with at least one of (i) a valve associated with the patient's heart, and (ii) a vessel associated with the patient's heart.

A beneficial mode of this aspect allows the medical device to be chosen from the array at least in part based upon a known measurement for a geometric parameter associated with at least one of the mitral valve and the coronary sinus. With respect to choosing the medical device at least in part based upon a known measurement for a geometric parameter associated with the mitral valve, such geometric parameter may be directly or indirectly associated with a mitral valve annulus of the mitral valve, and may in one particular further embodiment be a diameter of the mitral valve annulus.

There is provided in accordance with one aspect of the present invention, a method of treating mitral valvular insufficiency. The method comprises the steps of tranvenously advancing a prosthesis into the coronary sinus, and deploying at least a

portion of the prosthesis within the coronary sinus to reduce the diameter of the mitral annulus. Although deployment can be accomplished in an open surgical procedure, the method preferably further comprises the step of percutaneously accessing the venous system prior to the transluminally advancing step. The venous system may be accessed  
5 by one of the internal jugular, subclavian, or femoral veins. Preferably, the deploying step further includes the step of advancing the prosthesis from a first configuration for transluminal implantation to a second configuration to apply pressure to the wall of the coronary sinus and thereby reduce and/or restrain the diameter of the mitral valve annulus.

10 In accordance with another aspect of the present invention, there is provided a method of performing transluminal mitral annuloplasty. The method comprises the steps of providing a catheter which carries a prosthesis, and percutaneously inserting the catheter into the venous system. The prosthesis is transluminally advanced into the coronary sinus, and deployed in the coronary sinus to influence the size of the mitral  
15 valve annulus. Preferably, the prosthesis is caused to exert a compressive force on the mitral valve annulus.

The compressive force of one embodiment is generated by a bias in the prosthesis. In an alternate embodiment, the compressive force is generated by tightening the prosthesis around the mitral valve annulus following the transluminally  
20 advancing step. The tightening step may be accomplished by axial movement of a tightening element with respect to the prosthesis.

In accordance with a further aspect of the present invention, there is provided a method of providing a therapeutic compressive force against a tissue structure which is distinct from a vessel wall. The method comprises the steps of positioning a device in  
25 the vessel, and exerting a force against the wall of the vessel to exert a force against an extravascular tissue structure. Preferably, the positioning step is accomplished percutaneously. In one application, the extravascular tissue structure comprises the mitral valve annulus. Thus, the present invention provides a method of performing annuloplasty of the mitral valve, comprising positioning a prosthesis in the venous  
30 sinus.

In accordance with a further aspect of the present invention, there is provided a method of treating a mitral valve. The method comprises the steps of providing an

elongate flexible vascular implant, having a first attachment site spaced axially apart from a second attachment site. The first attachment site is transluminally advanced through the coronary sinus and coronary venous system to form the implant into an open loop. The open loop is reduced in size to place tension on the coronary sinus, and the first attachment site is attached to the second attachment site to close the loop and retain tension on the coronary sinus.

In accordance with another aspect of the present invention, there is provided a method of treating the heart. The method comprises the steps of advancing an implant through an access site and into a coronary vein such as the coronary sinus. A forming element on the implant is thereafter proximally retracted while resisting proximal movement of the implant, thereby forming the implant into a desired shape. The access site is thereafter closed, leaving the formed implant within the coronary vein.

Preferably, the method further comprises the step of locking the implant into the desired shape prior to the closing step. The method may additionally comprise the step of severing at least a portion of the forming element prior to the closing step.

A further aspect of the invention is a medical system with a transluminally implantable device for limiting diastolic expansion of the left ventricle. This device includes an elongate body having a proximal end and a distal end. A first attachment site is provided proximate the distal end of the elongate body and a second attachment site proximate the proximal end of the elongate body. The first and second attachment sites are adapted to be secured together. In one mode of this aspect, the elongate body is flexible a locking clip is provided for securing the ends. The body adapted to loop through the coronary venous system, and the locking clip is adapted to cinch onto the proximal end and distal end of the flexible elongate body until a requisite amount of tension is produced to limit diastolic expansion of the left ventricle.

Further features and advantages of the present invention will become apparent to those of ordinary skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

#### Brief Description of the Drawings

Figure 1 is a schematic illustration of the heart, showing one embodiment of the mitral annuloplasty device of the present invention deployed within the coronary venous system.

5 Figure 2 is a schematic illustration of the mitral annuloplasty device shown in Figure 1.

Figure 3 is an overall view and cross-sectional view through a transvenous delivery sheath.

10 Figure 4 is a schematic illustration of the delivery sheath and two different embodiments of the implant for extravascular remodeling, one with a forming element and one without.

Figure 5 is a schematic illustration of an alternative embodiment of the present invention positioned in an open-loop configuration through the delivery sheath.

15 Figure 6 is a schematic illustration of a heart, having an alternate embodiment of the mitral annuloplasty and cardiac reinforcement device of the present invention positioned within the coronary sinus and contiguous venous system.

Figure 7 is a schematic cross-sectional view of one embodiment of a locking device in accordance with the present invention.

Figure 8 is a fragmentary view of a portion of the lock illustrated in Figure 7, with a locking tool.

20 Figure 9 is a fragmentary view as in Figure 8, showing an unlocking tool.

Figure 10 is a perspective view of another device assembly according to the invention.

Figure 11A is a segmented view of the device assembly shown in Figure 10, and shows a partially exploded view of a region of the assembly.

25 Figure 11B shows a transverse cross-sectional view taken along 11B-11B in Figure 11A.

Figure 12A shows an exploded perspective view of one region of another device assembly according to the invention.

30 Figure 12B shows a partially cross-sectioned side view of a region of a device assembly similar to that shown in Figure 12.

Figure 13A shows a partially cross-sectioned exploded side view of a distal prosthetic implant region of a device assembly similar to that shown in Figure 10, and



shows the distal prosthetic implant region in a first configuration during a first mode of use.

Figure 13B shows a similar view as that shown in Figure 13A, and shows the distal prosthetic implant region in a second configuration during a second mode of use.

5

#### Detailed Description of Preferred Embodiments

The present invention provides a method and apparatus for performing mitral annuloplasty and remodeling of the left ventricle using a device that may be introduced percutaneously, and placed within the coronary venous system of the heart. The device  
10 exerts compressive force on the mitral annulus and left ventricle, reducing the severity of mitral regurgitation and the size of the left ventricular cavity. The device thus enables reduction of the mitral annulus and constraint of the diastolic expansion of the left ventricle yet without the morbidity and other risks associated with open chest surgery.

15 The present inventors have determined that the coronary sinus and veins provide an ideal conduit for the positioning of an intravascular prosthesis for remodeling the mitral annulus, since they are positioned adjacent the mitral annulus and interventricular septum. The coronary sinus is contained within the atrioventricular groove, and is in close proximity to the posterior, lateral and anterior aspects of the mitral annulus. The  
20 coronary sinus and coronary veins are cannulated currently during any of a variety of percutaneous transvenous diagnostic and therapeutic procedures. Permanent placement of pacemaker and defibrillator leads within the coronary sinus and veins is both safe and well tolerated.

The annuloplasty system consists of several components. There is a delivery  
25 system intended to be introduced percutaneously into a central vein such as the internal jugular, subclavian or femoral veins and to cannulate the coronary sinus. The implant of the present invention is deployed from the delivery catheter into the coronary venous system. Additional tools may be placed through or along the delivery catheter to position the device, apply elements in place, and to control and/or cut the tensioning  
30 elements from the delivery system as will be discussed.

Referring to Figure 1, there is illustrated a schematic view of the heart 10, having a mitral annuloplasty and cardiac reinforcement device 40 positioned therein.

The heart 10 generally comprises a right atrium 12, in communication with the superior vena cava 14 and inferior vena cava 16. The left ventricle 18 is positioned below the left atrial appendage 20. Relevant portions of the coronary vasculature include the coronary sinus 22, which extends from the ostium 24 to the junction 26 of the coronary sinus and the great cardiac vein 28. There may be anastomotic connections 29 between the great cardiac vein 28 and the middle cardiac vein 30, as is well understood in the art.

One embodiment of a mitral annuloplasty and cardiac reinforcement device 40 in accordance with the present invention is illustrated generally in the coronary sinus 22. In particular, the device 40 extends from a proximal end 42 to a distal end 44. The proximal end 42 lies against the posterior aspect of the interatrial septum 46. The midportion 48 of the device 40 is positioned within the coronary sinus 22. The transitional section 50 of the device 40 lies at the junction 26 of the coronary sinus 22 and the great cardiac vein 28. The distal end 44 of the device 40 is lodged in the great cardiac vein 28.

The transitional region 50 is designed to reside in the proximal portion of the great cardiac vein 28. By deflecting out of the plane of the coronary sinus 22, it serves as an anchor 52 and prevents the device 40 from slipping out of the coronary sinus 22 when tension is applied. This embodiment of an anchor 52 is very flaccid and flexible, thereby minimizing the risk of erosion of the device 40 through the wall of the great cardiac vein or other aspect of the coronary venous system. The proximal end 42 of the device 40 lies outside the ostium 24 of the coronary sinus 22 and is curved upward so as to anchor against the posterior aspect of the interatrial septum 46. The proximal end 42 is semicircular in shape and elliptical in profile so that no edges will promote erosion of adjacent tissue.

As an alternative anchor 52 to the distal extension of the device 40, any of a variety of structures may be provided. In general, the deployed device 40 will contact the wall of the coronary sinus 22 along the inside radius of its arcuate path. Thus, a tissue contacting surface 54 on the concave side of the deployed device 40 may be provided with any of a variety of friction enhancing surface structures, such as a plurality of transverse ridges, teeth or other projections, or modified surface textures to enhance friction. Alternatively, tissue engaging or piercing structures such as barbs

may be provided on the surface 54 to engage the wall of the coronary sinus 22 to resist movement of the device 40.

While use of such structures as anchors may provide some benefit in certain applications, embodiments herein shown and described are believed to be particularly useful in one aspect specifically because they operate without the need for such aggressive tissue engagement. It is apparent to one of ordinary skill based upon this disclosure that the present embodiments provide independent device manipulation and shape control that allow for sufficient forces to be applied to the mitral valve without requiring the possibly harmful effects of puncturing and grabbing tissue within the sinus for the remodeling process. In one regard, the independent action of a barbless design allows for adjustment in both the tightening and loosening directions with reduced risk of significant tissue damage or erosion. In another regard, the present device according at least to certain embodiments beneficially maintains its length throughout its modified range of shapes while the sinus and adjacent valve annulus reduce their dimensions under the force of remodeling. In still a further regard, the independent action and lack of tissue piercing and grabbing anchors allow for the device to be removed from the patient after initial implantation within the sinus, such as for example in the event of complications or in applications intended to be temporary remedial measures, such as for bridging a patient. Further to this regard, various shapes and sizes of devices may be required in a given patient before the appropriate one is found according to the observed *in vivo* response to implantation.

The specific dimensions, construction details and materials for the mitral annuloplasty and cardiac reinforcement device 40 can be varied widely, as will be appreciated by those of skill in the art in view of the disclosure herein. For example, dimensional adjustments may be made to accommodate different anatomical sizes and configurations. Materials and construction details can be varied to accommodate different tensioning mechanisms and other considerations.

In general, the device 40 has an overall length from proximal end 42 to distal end 44 within the range of from about 2 cm to about 10 cm, in an embodiment such as that illustrated in Figure 2 in which the anchor 52 comprises a distal extension of the body 66 for lodging within the great cardiac vein 28. One embodiment of the device 40 includes an elongate flexible body 66 about eight centimeters in length. In this

embodiment, the body 66 is preferably elliptical in cross section so that it will bend in the plane of the coronary sinus 22 and mitral annulus when force is applied to the tensioning element within it (discussed below). Distally the device tapers and transitions to a round cross-section.

5 Referring to Figure 2, there is illustrated an embodiment of the device 40 having a forming element 56 therein. Manipulation of the forming element 56 allows the device to be moved from a flexible orientation to enable percutaneous insertion into the vascular system and navigation into the coronary sinus, to an arcuate configuration for compressing at least a portion of the mitral annulus. The device 40 may be advanced  
10 from the first, flexible configuration to the second, arcuate configuration by either axial proximal retraction or distal advancement of the forming element 56 with respect to the body 66, depending upon the particular design.

In general, the device 40 comprises an elongate flexible support 58, extending from a proximal end 42 at least as far as a point of attachment 60. The support 58 may  
15 be a portion of the body 66 or may be a distinct component as will be discussed. The support 58 has a fixed length, and is relatively axially noncompressible or expandable. Thus, proximal retraction of the forming element 56 compared to the proximal end of the support 58 will cause the support 58 to deflect in a first direction. Distal axial advancement of the forming element 56 with respect to the support 58 will cause lateral  
20 deflection of the support 58 in a second direction. This basic steering configuration can be embodied in many forms, which can be optimized by those of skill in the art to suit a particular construction for the body 66 depending upon the desired dimensions and clinical performance.

The forming element 56 extends from the proximal end 42 through the device  
25 40 to the point of attachment 60. At the point of attachment 60, the forming element 56 is mechanically linked, and preferably, directly linked to the support 58. A proximal extension 64 of the forming element 56 extends from the proximal end 42 of the device 40, such as through an aperture 62. Proximal retraction of the forming element 56 through the aperture 62 causes the device 40 to bend from an implantation orientation  
30 for navigating the coronary vasculature during implantation to a formed orientation for compression and constraint of the coronary sinus 22 and adjacent structures.

In the formed orientation, the device 40 preferably provides a compressive force against the mitral annulus as has been discussed. This is accomplished by forming the device into an arcuate configuration. Generally, the best fit curve of constant radius to which the formed device conforms has a radius within the range of from about 1.0 cm to about 2.0 cm.

The forming element may comprise any of a variety of components, such as a polymeric or metal wire or strand, a multifilament braided or woven line, a metal or polymeric ribbon, or other structure capable of retaining the device 40 under tension in the coronary sinus 22.

The device 40 further comprises a support 58, which may be the body 66 of the device 40 or a separate element positioned therein. In an embodiment in which the support 58 is a separate element contained within the device 40, support 58 may comprise any of a variety of generally axially non-compressible elements such as a metal or polymeric wire or column, ribbon, or "bottomed out" spring which facilitates lateral bending but inhibits axial compression upon proximal retraction of forming element 56. A metal ribbon comprising stainless steel, nitinol, or other known materials may be desired in certain embodiments, due to its ability to influence the plane of curvature of the device 40 when in the formed orientation.

The proximal extension 64 of the forming element 56 extends proximally throughout the length of the deployment catheter, to a control or free end which remains outside of the patient during the deployment procedure. Following placement of the device 40 in the coronary sinus, proximal traction on the proximal extension 64 will reconfigure the device 40 into the formed orientation within the coronary sinus, as will be discussed in connection with the method of the present invention. After a sufficient tension has been placed on the coronary sinus, the forming element 56 is preferably axially locked to the device 40, to resist distal movement of the forming element 56 through aperture 62. Any of a variety of locks 70 may be provided. Preferably, the lock 70 is provided on or near the proximal end 42, and, in particular, at or about the aperture 62. The lock may comprise any of a variety of structures, such as a suture knot, locking clamp or ring, an interference fit, ratchet and pall structures, an adhesive bond, or a compression fit, as will be apparent to those of skill in the art in view of the disclosure herein.

5 The lock 70 (on any of the embodiments herein) may be initially disengaged, so that the forming element 56 may be retracted or advanced freely through the aperture 62 while the physician adjusts the tension on the device 40. After the desired tension is achieved, the lock 70 is activated to engage the forming element in a manner which will depend upon the lock design. Alternatively, the lock 70 may be biased into an engaged configuration, such as with ratchet or cam structures, so that the forming element can only be retracted proximally. Preferably, however, the lock will allow the forming element to be released so that the physician can release tension in the device 40 in the event of momentary over tightening.

10 Referring to Figures 7 – 9, there is disclosed one embodiment of a releasable lock 70 in accordance with the present invention. Although the lock 70 is illustrated as a discrete component of the system, it can alternatively be formed integrally with or attached to the proximal end of the body 66. The lock 70 comprises a body 114, which may be in the form of an annular collar with a central aperture for axial movement over  
15 the forming element 56. The body 114 is provided with one or two or three or more releasable locking elements 126 which ramp radially inwardly in the proximal direction.

Each locking element 126 is provided with at least one engagement surface 122 for engaging the forming element 56. The forming element 56 may be provided with  
20 any of a variety of friction enhancing surface textures or structures to enhance the locking function. Thus, a locking zone along the forming element may be provided with an etched surface or friction enhancing coating. Alternatively, structures such as a plurality of beads or teeth can be provided to permit an interference fit with the engagement surface 122.

25 The engagement surface 122 is movable between a first, disengaged configuration and a second, engaged configuration. This may be accomplished by pivoting the locking element 126 about a fulcrum 118. In the illustrated embodiment, fulcrum 118 is formed by an annular ring 119. Alternatively, the fulcrum 118 can be formed by plastic deformation of an integral structure, such as a living hinge formed by one or more annular grooves in the body 114.

30 The locking elements 126 may be biased in the locked direction, unlocked direction, or neutrally. Locking may be accomplished by pressing distally on a locking surface 124 such as with a locking tool 125 (Figure 8) which applies distal pressure on

the ramped locking element 126 at a point which is displaced radially inwardly from the fulcrum 118. Unlocking may be accomplished by distally advancing an unlocking tool 128 against a release surface 120 which is displaced radially outwardly from the fulcrum 118. In one embodiment, the locking tool 125 and unlocking tool 128 are conveniently formed from concentric tubular elements as will be apparent to those of skill in the art. The tubular elements or proximally extending control wires extend proximally to controls outside of the patient. Alternatively, any of a variety of ramped engagement surfaces and tools can be readily configured to accomplish the lock and/or release functions in view of the disclosure herein.

The length of the device 40 from proximal end 42 through the point of attachment 60 is generally within the range of from about 2 cm to about 10 cm, and, preferably within the range of from about 6 cm to about 8 cm. The shape of the device 40 is preferably designed to minimize trauma to the vascular intima, both during implantation and following placement. This may be accomplished by rounding all edges which may come into contact with the vessel wall. Thus, the cross-section through the mid portion 48 of the device, for example, may be elliptical, semicircular or otherwise rounded, or rectangular with rounded corners. In general, the maximum area of a cross-section of the device 40 will be no more than about 15 mm<sup>2</sup>, and preferably no more than about 10 mm<sup>2</sup>, for implantation within a human adult.

The device 40 may be manufactured in accordance with any of a variety of techniques, which will be apparent to those of skill in the art in view of the disclosure herein. For example, the body 66 may be formed by extrusion, injection molding, or other techniques. In one embodiment, the forming element 56 is secured at point of attachment 60 to an elongate flexible support 58 and coextruded within a polymeric body 66. Alternatively, the forming element 56 and support 58 subassembly may be positioned within a mold cavity, and injection molded to produce the final device 40. The body 66 may comprise any of a variety of biocompatible materials such as various densities of polyethylenes, nylon, polyethylene terephthalate, PEBAX, and others which will be apparent to those of skill in the art.

Alternatively, the forming element 56 and support 58 may be surrounded by a tubular jacket of ePTFE or Dacron fabric, or other material which is wrapped or stitched onto the forming element 56 to produce the final device 40. As a further

alternative, the subassembly which includes the forming element 56 and, if present, support 58 may be positioned within a suitable length of tubing formed such as by extrusion. The tubing may be drawn down to a reduced diameter at the distal end 44. Additional post extrusion steps may be used to produce the desired cross-sectional configuration. Manufacturing techniques for the present invention will be apparent to those of skill in the art in view of the disclosure herein.

Any of a variety of additional features may be added to the device 40, depending upon the desired clinical performance. For example, the outside surface of the body 66 may be provided with any of a variety of coatings, such as Paralene, PTFE or others to improve lubricity; heparin or other antithrombogenic agents; elastomers such as silicone, neoprene, latex or others to soften the surface and reduce the risk of trauma to the vascular intima, and the like. Adhesion enhancing surfaces may be provided, such as ePTFE patches or jackets, to promote cellular ingrowth for long term anchoring. In addition, depending upon the deployment system design, the body 66 may be provided with a guidewire lumen extending axially therethrough, to allow the body 66 to be advanced distally over a guidewire during placement at the treatment site.

The device 40 may be implanted within the coronary sinus 22 either through direct surgical (e.g. thoracotomy with or without sternotomy) access, such as in combination with another surgical procedure, via port access, or remotely by way of a percutaneous or surgical cut down access to the venous system. Preferably, the device 40 is implanted in a transluminal procedure, such as by way of a percutaneous access at one of the internal jugular, subclavian, or femoral veins.

Referring to Figure 3, there is disclosed a deployment system 72 for deploying the device 40 of the present invention. The deployment system 72 comprises an introducer sheath or catheter 74 for percutaneous venous access procedures. In some circumstances, however, the system 72 includes a first introducer sheath 74 for simply gaining percutaneous access into the vasculature at a remote location from the heart, and a slideably engageable second introducer sheath or guiding catheter is deliverable through such a percutaneous introducer sheath. Introducer sheath 74 has an elongate flexible tubular body 76 extending from a proximal end 78 to a distal end 80. A preset curve 82 is provided near the distal end 80 of the tubular body 76, as is known in the cardiac access catheter arts. At least one lumen 84 extends through the tubular body 76.



In one embodiment, the lumen 84 has a noncircular cross section, such as an ellipse having the major axis perpendicular to the plane of curvature of the introducer sheath 74.

Introducer sheaths are well known in the art, and may be manufactured such as by extrusion, with or without a braided reinforcement structure in the wall. The length and diameter of the introducer sheath 74 may vary considerably, depending upon the dimensions of the device 40 as well as the access point for percutaneous access into the vascular system. For a femoral vein access, for example, the introducer sheath may have a length within the range of from about 80 cm to about 120 cm. Preferably, the outside diameter of the introducer sheath 74 is no more than about 10 French (approximately 3.3 mm).

A pusher or dilator 86 as shown provides specific embodiments for a broader aspect that is a delivery member used in an overall assembly for delivering, i.e. advancing or pushing, the device prosthesis into the coronary sinus in a transluminal procedure, as is apparent to one of ordinary skill based upon the figures and accompanying disclosure herein. Delivery member or dilator 86 has an axial length of from about 10 cm to about 20 cm greater than the axial length of the introducer sheath 74. Dilator 86 has an outside diameter which is less than the inside diameter of the lumen 84, so that the dilator 86 may be freely axially advanced through the lumen 84. The dilator 86 is provided with a central lumen 88, for axially moveably receiving the proximal extension 64 of forming element 56.

When assembled for deployment of a device 40 within the coronary vasculature, a device 40 is positioned within a distal portion of the lumen 84. The dilator 86 is positioned proximal to the device 40 within the lumen 84, and the proximal extension 64 of forming element 56 extends proximally through central lumen 88 of dilator 86. During proximal movement of the introducer sheath 74 with respect to the dilator 86, a distal surface 90 on dilator 86 resists proximal movement of the device 40. Thus, the device 40 may be deployed from the distal end 80 of introducer sheath 74. In addition, proximal retraction of the proximal extension 64 while proximal movement of the device 40 is prevented by surface 90 causes the device 40 to advance from its deployment configuration to its implanted configuration.

Once the coronary sinus 22 has been cannulated by the introducer sheath 74, the dilator that is loaded over the forming element is advanced through the sheath 74. This is used to push the device 40 to the proper location with the distal tip 44 in the distal portion of the great cardiac vein 28. Using counter traction of the forming element and the dilator, the device is curved until the appropriate degree of annular remodeling has been achieved. A locking ring 70 on the forming element that is interposed between the dilator and the device prevents the forming element from slipping distally once the device 40 has been curved. A locking ring 70 that can be released by using a dilator with a different tip geometry may also be employed. After satisfactory deployment and deflection of the device 40, the forming element 56 is cut with a cutting tool (not illustrated) that is placed through the introducer sheath.

A second embodiment of the device does not contain an axially moveable forming element. Instead, a core of springy memory material such as nitinol or other NiTi alloy is pre-formed to have the required configuration. When the device is pushed out of the delivery catheter into the coronary venous system, the spring force within the core applies the requisite force to remodel the annulus. This embodiment does not require a tensioning element or a tool to disconnect it from the delivery system. However, the magnitude of force applied to the annulus cannot be adjusted.

A third embodiment is deployed as a loop through the coronary venous system, to form a left ventricular girdle 100. See Figures 5-6. The ventricular girdle 100 comprises an elongate flexible body 102 having a proximal end 104 and a distal end 106. A first control line 108 extends proximally from the proximal end 104, and a second control line 110 extends distally from distal end 106. The first and second control lines 108 and 110 may be different portions of the same wire, which extends continuously throughout the length of the body 102. The wire may be a single strand or multi strand component, a length of hypodermic needle tubing, a spring coil, or other structure known in the medical guidewire arts. Preferably, the first and second control lines have a diameter within the range of from about 0.009" to about 0.018", although larger diameters may also be used particularly for the first control line 108.

The distal control line 110 is advanced through an introducer sheath into the great cardiac vein 28 and then through anastomotic connections 29 into the middle cardiac vein 30. Continued advancement results in the tip of the distal control line 110

emerging from the ostium 24 of the coronary sinus 22. The control line 110 is then harnessed with a snare and pulled retrogradely through the delivery catheter as illustrated in Figure 5. The body 102 is then pulled into the coronary venous system. The body is preferably larger in diameter than the first and second control lines 108 and 110, and preferably elliptical or otherwise noncircular in cross section. This shape enlarges the transverse tissue contact surface area and reduces the risk of erosion when tension is applied to the loop. Both the proximal and distal ends of the loop are threaded through a locking clip 112. A dilator is used to push the clip 112 through the delivery catheter to the level of the coronary sinus ostium. Using counter traction on the dilator and the first and second control lines 108 and 110, the clip 112 is cinched on the loop until the requisite degree of tension is produced. Finally, the device is separated from the delivery system using a cutting tool to cut the first and second control lines 108 and 110, and possibly proximal and distal ends 104 and 106 to the extent they extend proximally from clip 112.

The overall length of the embodiment illustrated in Figure 5 should be sufficient that both of the first control line 108 and second control line 110 can extend outside of the patient, while the body 102 extends throughout the pathway of the ventricular girdle 100 as illustrated in Figure 6. For a percutaneous femoral vein access, the overall length of the device is therefore preferably at least about 200 cm, and generally within the range of from about 220 cm to about 260 cm. The length of the body 102 from proximal end 104 to distal end 106 is preferably sufficient to form a closed loop as illustrated in Figure 6. Although both heart size and the shape of the vascular pathway will vary from individual to individual, the length of the body 102 is generally within the range of from about 6 cm to about 12 cm. The body 102 may be injection molded, extruded as a tube, or coextruded over the wire which forms first and second control lines 108 and 110. Preferably, the body 102 either comprises or is coated with a material which is sufficiently compliant to minimize trauma to the vascular intima. Also, the transverse width of a tissue contacting surface 114 on body 102 is preferably sufficient to distribute compressive force to minimize the risks of localized pressure necrosis within the coronary veins.

Figures 10-13B variously show another particular device assembly 200 that includes various aspects that are believed to be readily adapted for use according to various of the embodiments of the present invention as introduced above.

5 In general, Figure 10 shows an overall view of assembly 200 that includes a delivery assembly 210 which is engaged to a prosthesis 250. According to similar overall delivery systems and methods elsewhere herein described, prosthesis 250 is adapted to be delivered in a first condition and shape into a vessel at least in part by manipulation of delivery assembly 210. Once in the desired region of the target vessel, prosthesis 250 is adapted to be adjusted to a second condition and shape within the vessel in order to influence an adjacent tissue structure. As also elsewhere herein described, a particularly beneficial mode of such operation places the prosthesis 250 within a coronary sinus for the purpose of influencing a mitral valve annulus, more specifically in order to influence the shape of the annulus in order to reduce mitral valve regurgitation.

10 Figures 11A-B show the proximal aspects of device assembly 200, and in particular various details for delivery assembly 210 that includes an outer member 215 that is generally tubular with an inner lumen 216 that is sized to house an inner member 225. Inner member 225 in the variation shown is generally tubular and is substantially free to rotate within lumen 216 by providing rotational force to inner member 225 proximally outside of the patient's body. According to the example shown, this rotational force is applied to inner member 225 via a thumbwheel 205 that is provided on proximal hub assembly 201 that is coupled to proximal end portion 211 of delivery assembly 210. Thumbwheel 205 is rotationally coupled to inner member 25 within hub assembly 201, which rotational coupling may be achieved according to a number of adaption as would be apparent to one of ordinary skill.

25 Rotation of inner member 225 is transmitted into rotation of a rotational coupler 280 that is engaged within a proximal end portion 252 of prosthesis 250 as follows. Inner member 225 has an aperture 228 on its distal end portion that provides a female counterpart of a mated key interface between the inner member 225 and a male counterpart provided by a shaped proximal end 281 of a rotational coupler 280 that is also rotationally engaged within a proximal end portion 252 of prosthesis 250. The keyed fitting between inner member 225 and rotational coupler 280 allows for

transmission of rotational forces to rotational coupler 280. In order to maintain releasable axial engagement of this keyed coupling, a flexible member such as a filament 240 is looped through an aperture 283 through proximal end 281 of rotational coupler 280 with both filament ends 242 and 244 extending proximally through inner member 225 to a location in proximal coupler. This filament 240 is generally held in sufficient tension to keep the distal keyed fitting engaged, though it is further contemplated that the mere presence of the filament may provide an interference against uncoupling if there is a sufficiently tight tolerance in the male/female interface of the keyed fitting.

Rotational coupler 280 is rotationally engaged within proximal end portion 251 of prosthesis 250 through proximal port or aperture 251 such that rotational coupler 280 is adapted to rotate within and relative to the prosthesis. This relative rotation is converted to force a deflection of prosthesis 250 into the desired shape of the second configuration in situ as follows.

According to one aspect of the rotational coupling, the prosthesis 250 is preferably held to resist rotation while rotational coupler 280 is rotated within the prosthesis 250. This may be achieved simply by frictional forces of surrounding tissue as prosthesis 250 is delivered into the desired vessel such as the coronary sinus. According to another example, this may be achieved by providing a releasable interface such as a friction fit between outer member 215 and proximal end portion 252 of prosthesis 250, wherein the frictional engagement of outer member 215 and prosthesis 250 are held in a relatively fixed position while inner member 225 and rotational coupler 280 are rotated. This embodiment is shown in Figure 11A. In addition or in the alternative to the friction fit interface, a keyed interface may be employed as shown in Figures 12A-B. According to this mode, a shaped proximal fitting 253 on the proximal end 252 of prosthesis 250 is adapted to mate as a male counterpart into a shaped aperture or fitting on the distal end 212 of outer member 215. This keyed interface allows for rotational coupling between the members in a similar manner as just described for the inner member 225 and rotational coupler 280, and may allow for a more releasable coupling with reduced friction upon axial detachment of the members.

According to another aspect, the rotational forces from rotational coupler may be converted to deflection forces on the prosthesis 250 according to one example as

illustrated in the specific illustrative embodiment of Figures 10-13B, and in particular detail in Figures 13A-B. Prosthesis 250 includes a generally tubular wall or body 260 that has an inner lumen 262 and extends from the proximal end portion 252 to the distal end portion 254 of prosthesis 250. Secured along proximal end portion 252 is a nut fitting 263 that has a grooved inner bore 264 which communicates with inner lumen 262. Further to this specific embodiment, rotational coupler 280 is a screw member with outer groove or grooves 285 engaged within the mating grooved inner surface (not shown) of a bore lumen 264 such that a distal end of screw member 285 extends distally within lumen 262 and terminates at a second key fitting 287 similar to the shaped proximal end portion 282 and also having an aperture 288. Similar to the proximal end of rotational coupler 280, another flexible member or filament 290 is looped through aperture 288 such that two arms 292,294 extend distally therefrom to an attachment point along distal end portion 254 of prosthesis 250. Because nut fitting 263 is fixed in relation to outer tubular body 260, and because that tubular body is held relatively fixed position as provided above, rotation of rotational coupler 280 moves coupler 280 proximally relative to body 260. This proximal axial translation of rotational coupler pulls tension on filament 290, which pulls tension on the body 260 due to the distal attachment. This tension on outer body 260 forces a deflection of that body. Therefore, rotational forces are translated into tensile forces which are translated into radial deflection forces relative to the longitudinal axis L of the device.

The forced deflection just described may be controlled in a particular plane by providing a composite structure within prosthesis 250 that is engineered to respond, i.e. yield, to these forces in a prescribed way. In the specific desirable embodiment shown, a relatively rigid spine member 270 is provided within lumen 262 of outer tubular body 260. This spine member 270 is more rigid and more resistant to axial forces than the material of outer tubular body 260 alone, and therefore providing spine member 270 along only one radial aspect of the prosthesis 250 creates a bias on the device to deflect away from that spine toward a more compressive region of the device. Such composite design may further include a laminant structure, imbedded wire reinforced wall structure, or may be achieved by engineering material variations in the device, such as for example by thinning, thickening, hardening, or softening the material at one location

along the outer tubular body 260 relative to another region to force deflection at a desired location.

As may be achieved by other controllable embodiments elsewhere herein described, deflection according to the present embodiment may be adjusted according to a healthcare provider's desires, and is adjustable in either direction -- by either tightening the radius of curvature R or opening it. According to this specific embodiment however, the adjustability of and choice between tightening and loosening of the deflection depends upon the direction and extent of rotation placed upon the rotational force transmission system.

In any event, once the desired deflection is achieved and desired therapeutic results are observed, the prosthesis 250 may be detached from the delivery assembly 210 by severing the torque or rotational force transmission system at the keyed fitting between the inner member 225 and the rotational coupler 280. This is accomplished by first releasing at least one arm 242,244 of the proximal filament 240 while withdrawing the other arm, thereby threading the filament 240 through aperture 283 (as shown in bold arrows in Figure 13B) until it is unthreaded completely from the aperture 283. This allows inner member 225 to be withdrawn proximally from rotational coupler 280 to detach therefrom and thereby implant prosthesis 250. Alternatively, as with other adjustable deflection systems herein described, the prosthesis may be held in its therapeutic condition for a temporary period of time (which may nevertheless be prolonged during a hospital stay), during which time mitral valve regurgitation may be minimized, such as for example for the purpose of bridging the patient in a temporarily improved condition until other treatments may be performed, e.g. annuloplasty, valve surgery, heart transplant, etc. In this alternative temporary setting, at the appropriate time the deflected, contracted prosthesis may be adjusted back open from its cinched position around the valve, and then withdrawn without implantation by withdrawing the entire system, delivery assembly still engaged to the prosthesis. Moreover, it is further contemplated that such a temporary prosthesis may be modified to remove the detachment mechanisms herein described, which may provide for a simpler and lower cost device.

Device assembly 200 is also shown in various of the Figures 10-13B to include a distal guidewire tracking member with a guidewire lumen 265 which is adapted to

slideably engage a guidewire 230 in order to be placed in a percutaneous transluminal procedure into the desired vessel location, such as within the coronary sinus. The particular guidewire lumen shown is integral within the distal aspects of prosthesis 250 as a "rapid exchange" or "monorail" design that allows for relatively independent movement of the guidewire and catheter in vivo. Moreover, this design removes the need for the guidewire to ride coaxial through the entire device assembly 200, as would be the case for example in an "over the wire" type system. The type shown beneficially allows for detachable engagement of prosthesis 250, which is preferably achieved after withdrawing the guidewire from the distal lumen 265.

In each of the foregoing implantation methods, the physician preferably monitors the degree of regurgitation during the step of tightening the implant. Although any reduction in mitral regurgitation may be desirable, regurgitation is preferably reduced to something less than moderate (less than 2+). In any event, at least a one grade reduction is preferably achieved. On the other hand, reconfiguration of the implant should not be accomplished to an extent sufficient to produce mitral stenosis, or any flow limitation of hemodynamic significance.

Thus, the method of implantation preferably further comprises the steps of monitoring the degree of mitral regurgitation during the implantation and/or reconfiguration steps. The degree of mitral regurgitation may be monitored such as by transesophageal echo cardiography, surface echo cardiography, intracardiac echo cardiography, fluoroscopy using radiocontrast in the left ventricle (LVgram), or left atrial or pulmonary capillary wedge pressure tracings, as are understood in the art, during the incremental restriction of the mitral annulus and/or left ventricle step. Once a sufficient reduction in regurgitation has been achieved for a particular patient in the physician's judgement, the device is locked and the proximal extension of the forming element is severed from the device and removed from the patient.

The method may additionally comprise the step of measuring the coronary sinus and/or other coronary vein, and selecting an appropriately sized implant from an array of implants of varying sizes. Such parameters may include diameter, length, or radius of curvature of the arc of the sinus. The appropriately sized implant is thereafter positioned within the target vein. The implant is thus preferably provided in a graduated array of sizes, so that the optimal size can be selected for each patient. The



size of the coronary sinus or other vein can be measured using any of a variety of techniques, such as echo cardiogram, MRI, CT scan, or angiography as is understood in the art. Moreover, as is apparent to one of ordinary skill, measuring a parameter of the coronary sinus generally provides indicia of certain parameters of the mitral valve and its annulus, such as for example mitral valve diameter, in which case either the coronary sinus parameter or the mitral valve parameter may provide the requisite information for choosing an appropriately dimensioned device from the kit. It follows that such mitral valve parameters may further be measured directly, such as by various of the methods just described, in order to generate the values used for choosing the appropriate device. Once a parameter for an anatomical feature is measured as herein described, its value is generally estimated according to the accuracy of the respective measuring tool -- it is contemplated that persons without specialized medical skills or training can choose the appropriate medical device from the kit once armed with this estimated value. For example, packaging for each device of the kit may indicate the respective dimensions that are unique to that device with respect to other devices of the kit, and the estimated value of the measured anatomical parameter may simply be compared.

It is contemplated and apparent that various of the embodiments herein described are adapted to accomplish device manipulation within the coronary sinus for mitral annulus reduction without substantially altering the length of the device within the sinus. This may provide a benefit by increasing the useful purchase of the device along the coronary sinus and circumferentially around the mitral annulus as the sinus length and/or annulus diameter may be reduced during remodeling from the radial deflection of the prosthetic device. This may also mean that the dimension of the device in a kit of devices may not directly correspond to the estimated value of the anatomical parameter that is measured. For example, the compared value of the measured device parameter may be shorter than an estimated coronary sinus length due to a possible shortening of the sinus during device treatment. Or, the anatomical parameter may be estimated from an initial value based upon an anticipated or desired final result from treatment and such procedurally related value be used for choosing the appropriate device (e.g. comparing an estimated final length of the sinus or mitral valve diameter with a known dimension of the device in the remodeling configuration when used *in situ*).

As a further aspect to the present invention, the implant is preferably combined with an appropriate drug therapy for treating congestive heart failure. Residual regurgitation and other hemodynamic functions are preferably measured following implantation of the implant of the present invention. Heart medications are preferably  
5 adjusted to take into account the reduction in regurgitation and/or reduction in left ventricle volume in formulating an ongoing drug therapy for the patient.

Still further, the aspect of the present invention that allows for temporary use in the sinus for mitral valve remodeling as a bridging regime in combination with other permanent treatments such as more conventional annuloplasty or valve replacement via  
10 surgery. Such combined systems of devices and respective methods of use, which may further be combined with the pharmaceutical drug regimes, provide an overall treatment regime that provides a highly beneficial result for management of patients with harmful mitral valve regurgitation.

In accordance with further aspect of the present invention, there is provided a  
15 method of constricting the left ventricle. Left ventricular constriction may be desirable in patients without mitral regurgitation. One implementation of this method comprises implanting the ventricular girdle 100 as illustrated, for example, in Figures 5 through 6 and previously discussed herein.

Any of the embodiments disclosed herein may additionally be provided with one  
20 or more externally facing electrically conductive axially extending strips or annular bands, to enable the device 40 to function additionally as a cardiac pacing or other cardiac electrode. The electrically conductive band or bands are placed in electrical communication with a pacing source or diagnostic instrument by way of one or more electrical conductors extending away from the device 40. The conductors may be  
25 electrically connected to any of a wide variety of electronic cardiac rhythm management devices, which are well known in the art.

Although the present invention has been described in terms of certain preferred embodiments, it may be incorporated into other embodiments or performed through other steps by persons of skill in the art in view of the disclosure herein. The scope of  
30 the invention is therefore not intended to be limited by the specific embodiments disclosed herein, but is intended to be defined by the full scope of the following claims.

WHAT IS CLAIMED IS:

1. A medical device (40) for remodeling an extravascular tissue structure adjacent to a vessel (22) in a patient, comprising:

an elongate body (66) extending between a proximal end (42) and a distal end (44), and that is adjustable between a first configuration having a first shape such that the elongate body (66) is adapted to be delivered at least in part into the vessel (22) and a second configuration having a second shape such that the elongate body (66) is adapted to exert a force from within the vessel (22) onto the extravascular tissue structure in order to remodel the extravascular tissue structure.

2. A medical device (40) as in Claim 1, wherein

the elongate body (66) is adapted to be positioned in the first configuration at least in part within a coronary sinus (22) and is adapted to remodel a mitral valve annulus adjacent to the coronary sinus (22) when the elongate body (66) is located at least in part within the coronary sinus (22) and is adjusted to the second configuration.

3. A medical device (40) as in Claim 2, wherein

the elongate body (66) is adapted to be permanently implanted in the patient at least in part within the coronary sinus (22) in the second configuration in order to provide chronic remodeling of the mitral valve annulus.

4. A medical device (40) as in Claim 2, wherein

the elongate body (66) is selectively adjustable between the first and second configurations while the elongate body (66) is located at least in part within the coronary sinus (22), and is adapted to be temporarily implanted at least in part within the coronary sinus (22) in the second configuration for temporary remodeling of the mitral valve annulus and to be thereafter removed from the coronary sinus (22) in the first configuration.

5. A medical device (40) as in Claim 2, wherein the elongate body (66) within the coronary sinus (22) comprises a substantially similar length between the first and second configurations.

6. A medical device (40) as in Claim 2, wherein the elongate body (66) within the coronary sinus (22) is relatively non-expandable while the elongate body (66) is adjusted between the first and second configurations.

7. A medical device (40) as in Claim 2, wherein the elongate body (66) within the coronary sinus is relatively non-compressible while the elongate body (66) is adjusted between the first and second configurations.

5 8. A medical device (40) as in Claim 2, wherein the elongate body (66) has a length between the proximal and distal ends (42,44) that is less than about 10 cm.

9. A medical device (40) as in Claim 2, further comprising a lock (70) for retaining the elongate body (66) in the second configuration at least in part within the coronary sinus (22).

10 10. A medical device (40) as in Claim 2, wherein in the second configuration the second shape for the elongate body (66) at least within the coronary sinus defines an arc.

11. A medical device (40) as in Claim 10, wherein a best fit constant radius curve corresponding to the arc has a radius within the range of from about 10 mm to about 20 mm.

15 12. A medical device (40) as in Claim 2, further comprising an anchor (42,52) for retaining the elongate body (66) at least in part within the coronary sinus (22).

13. A medical device (40) as in Claim 12, wherein the anchor (52) comprises a region (50) along a distal portion of the elongate body (66).

20 14. A medical device (40) as in Claim 12, wherein the anchor (42,52) comprises a friction enhancing surface (54) for engaging a wall of the coronary sinus (22).

15. A medical device (40) as in Claim 12, wherein the anchor (42,52) comprises at least one barb (54) for piercing a wall of the coronary sinus (22).

16. A medical device (40) as in Claim 12, wherein the anchor (42,52) is located at least in part at the proximal end (42) of the elongate body (66).

25 17. A medical device (40) as in Claim 16, wherein the anchor (42,52) is adapted to be positioned outside of the coronary sinus (22) and against a wall (46) of the right atrium in order to anchor the elongate body (66) at least in part within the coronary sinus (22).

30 18. A medical device (40) as in Claim 2, further comprising:  
a forming element (56) that is secured to the elongate body (66) at a point of attachment (60) and that is moveable relative to the elongate body (66) in order to

adjust the elongate body (66) within the coronary sinus (22) between the first and second configurations.

19. A medical device (40) as in Claim 18, wherein the forming element (56) between the point of attachment (60) and the proximal end portion (42) of the elongate body (66) is substantially circumferentially confined by the elongate body (66).

20. A medical device (40) as in Claim 18, wherein the forming element (56) has a proximal extension (64) that extends proximally from the elongate body (66) and externally of the patient when the elongate body (66) is located at least in part within the coronary sinus (22), and the elongate body (66) within the coronary sinus (22) is adjustable within the coronary sinus (22) from the first configuration to the second configuration by manipulating the proximal extension (64) outside of the patient.

21. A medical device (40) as in Claim 18, further comprising an anchor (42,52) for retaining at least a portion of elongate body (66) within the coronary sinus (22), and wherein the axial length of the elongate body (66) between the anchor (42) and the point of attachment (60) of the forming element (56) to the elongate body (66) is within the range of from about 2 cm to about 8 cm.

22. A medical device (40) as in Claim 18, wherein the elongate body (66) is adjustable from the first configuration to the second configuration principally by applying a force from the forming element (56) to the elongate body (66).

23. A medical device (40) as in Claim 22, wherein the elongate body (66) comprises a length along an axis and is adjustable from the first configuration to the second configuration principally by transmitting an axial force from the forming element (56) onto the elongate body (66) relative to the axis.

24. A medical device as in Claim 23, wherein the elongate body (66) is adjustable from the first configuration to the second configuration in response to proximal retraction of the forming element (56).

25. A medical device (40) as in Claim 23, wherein the elongate body (66) is movable from the first configuration to the second configuration in response to distal advancement of the forming element (56).

26. A medical device (40) as in Claim 22, wherein the forming element (56) is adapted to adjust the elongate body (66) from the first configuration to the second

configuration at least in part by providing a rotational force along at least a portion of the forming element (56).

27. A medical device (40) as in Claim 26, wherein the forming element (56) comprises:

5 a rotational force transmission member (225) with a proximal end portion and a distal end portion;

a rotational coupler (280) with a proximal end portion coupled to the distal end portion of the rotational force transmission member; and

10 an axial force transmission member (290) with a proximal end portion coupled to the distal end portion of the rotational coupler and a distal end portion coupled to the elongate body (66),

wherein the proximal end portion of the rotational force coupler is adapted to be positioned externally of the patient when the elongate body (66) is positioned within the coronary sinus (22) such that rotational forces may be imparted onto the rotational force transmission member (225), and the rotational coupler is adapted to convert rotational force from the rotational force transition member (225) to axial force onto the axial force transmission member (290), and the elongate body (66) is adjustable from the first configuration to the second configuration in response to the axial force from the axial force transmission member (290).

20 28. The medical device (40) as in Claim 18, wherein the elongate body (66) is adapted to be uncoupled in the second configuration from at least a portion of the forming element (56) as a permanent implant located at least in part within at least the coronary sinus (22).

25 29. A medical device (40) as in Claim 28, wherein the forming element (56) is adapted to be severed while the elongate body (66) is positioned at least in part within the coronary sinus (22) in the second configuration.

30 30. A medical device (40) as in Claim 29, further comprising a cutting tool which is adapted to cut the forming element (56) while the elongate body (66) is positioned at least in part within the coronary sinus (22).

31. A medical device (40) as in Claim 29, wherein the proximal extension (64) of the forming element (56) comprises a proximal member (225);

the forming element (56) further comprises a distal member (290) that is coupled to the proximal member (225) and is attached to the elongate body (66) at the point of attachment (60);

5 the proximal member (225) is adapted to transmit an applied force from outside the patient to the distal member (290) while the elongate body (66) along the midportion (48) is located within the coronary sinus;

the distal member (290) is adapted to substantially transmit the applied force from the proximal member (225) to the elongate body (66) in order to adjust the elongate body (66) from the first configuration to the second configuration within the coronary sinus (22);

10 and the distal member (225) is detachable from the proximal member (225) while the elongate body (66) is in the second configuration at least in part within the coronary sinus (22) in order to thereby sever the forming element (56).

32. The medical device (40) as in Claim 18, further comprising a lock (70) which is adjustable between (i) a disengaged configuration that allows the forming element (56) to be moveable relative to the elongate body (66) in order to adjust the elongate body (66) from the first configuration to the second configuration at least in part within the coronary sinus, and (ii) an engaged configuration that engages the forming element (56) to substantially fix the forming element (56) relative to the elongate body (66) when the elongate body (66) is in the second configuration at least in part within the coronary sinus.

33. A medical device (40) as in Claim 32, wherein the lock (70) is selectively adjustable between the engaged and disengaged configurations.

34. A medical device (40) as in Claim 32, wherein the lock (70) comprises a locking ring (114) having an aperture, and wherein the forming element (56) extends through the aperture.

35. A medical device (40) as in Claim 32, wherein the lock (70) comprises an interference fit.

36. A medical device (40) as in Claim 32, wherein the lock (70) comprises an adhesive bond.

37. A medical device (40) as in Claim 32, further comprising:

a locking tool (125) which is adapted to adjust the lock (70) from the disengaged configuration to the engaged configuration.

38. A medical device (40) as in Claim 32, further comprising:

an unlocking tool (128) which is adapted to release the lock (70) from the engaged configuration to the disengaged configuration.

39. A medical device (40) as in Claim 1, wherein the adjacent tissue structure has a wall that circumscribes a space having a diameter, and the elongate body (66) when adjusted from the first configuration to the second configuration within the body space (22) is adapted to compress the adjacent tissue structure to thereby reduce its diameter.

40. A medical device (40) as in Claim 2, further comprising:

a deployment system (72) cooperating with the elongate body (66) and which is adapted to at least in part deliver the elongate body (66) in the first configuration at least in part into the coronary sinus (22).

41. A medical device (40) as in Claim 40, wherein the deployment system (72) comprises a delivery member (86) that is coupled to the elongate body (66) and is adapted to advance the elongate body (66) into the coronary sinus (22).

42. A medical device (40) for remodeling a tissue structure adjacent to a body space (22) that is defined at least in part by a tissue wall in a patient, comprising:

an elongate body (66) extending between a proximal end portion (42) and a distal end portion (44) and that is adjustable between a first configuration having a first shape that is adapted to be delivered at least in part into the body space (22) and a second configuration having a second shape that is adapted at least in part to exert a force from within the body space (22) onto the adjacent tissue structure in order to remodel the adjacent tissue structure.

43. A method for providing a medical device (40) for use in treating a patient from within a vein (22) that is associated with the patient's heart, comprising:

providing an array of medical devices (40), each medical device (40) having an elongate body (66) that is adjustable in-situ from a first configuration having a first shape to a second configuration having a second shape, and each elongate body (66) of each medical device (40) of the array being constructed to have a unique size relative to the elongate bodies (66) of the other medical devices (40) of the array; and



choosing the medical device (40) from the array at least in part based upon a known measurement for a vein (22) that is associated with the patient's heart,

wherein the elongate body (66) of the chosen medical device (40) is adapted to be delivered in the first configuration into the vein (22) and is adjustable within the vein (22) from the first configuration to the second configuration such that the unique size is appropriate in order to remodel the mitral valve annulus from within the vein.

44. The method of claim 41, further comprising choosing the medical device (40) at least in part based upon comparing the measurement for the vein (22) with the unique size of the elongate body (66).

45. The method of claim 41, wherein the medical device (40) is chosen at least in part based upon a known measurement for a coronary sinus (22).

46. The method of claim 41, wherein the vein (22) has a central axis, and the known measurement comprises at least one of: a length of at least a portion of the vein (22), a radius of curvature of the vein (22) along the central axis, and a diameter of the vein (22) across the central axis.

47. The method of Claim 41, further comprising:

providing the array of medical devices (40) such that the elongated bodies (66) have a graduated array of respective sizes.

48. A method for providing a medical device (40) for use in treating a patient, comprising:

providing an array of medical devices (40), each medical device (40) having an elongate body (66) that is adjustable in-situ from a first configuration having a first shape to a second configuration having a second shape, and each elongate body (66) of each medical device (40) of the array being constructed to have a unique geometry relative to the elongate bodies (66) of the other medical devices (40); and

choosing the medical device (40) from the array at least in part based upon a known measurement for a parameter associated with at least one of (i) a valve associated with the patient's heart, and (ii) a vessel associated with the patient's heart,

wherein the elongate body (66) of the chosen medical device (40) is adapted to be delivered in the first configuration into the vessel (22) and is adjustable within the vessel (22) from the first configuration to the second configuration such that the unique geometry is appropriate in order to remodel the valve from within the vessel (22).

49. The method of claim 48, further comprising:

choosing the medical device (40) from the array at least in part based upon a known measurement for a geometric parameter associated with at least one of the mitral valve and the coronary sinus (22).

5 50. The method of claim 49, further comprising choosing the medical device at least in part based upon a known measurement for a geometric parameter associated with the coronary sinus (22).

10 51. The method of claim 50, wherein the coronary sinus (22) has a central axis, and the geometric parameter comprises at least one of: a length of at least a portion of the coronary sinus (22), a radius of curvature of the coronary sinus (22) along the central axis, and a diameter of the coronary sinus (22) across the central axis.

52. The method of claim 48, further comprising choosing the medical device (40) at least in part based upon a known measurement for a geometric parameter associated with the mitral valve.

15 53. The method of claim 52, wherein the geometric parameter is associated with a mitral valve annulus of the mitral valve.

54. The method of claim 51, wherein the geometric parameter comprises a diameter of the mitral valve annulus.

20 55. A method of reducing mitral annulus diameter, comprising:  
transluminally advancing a prosthesis into the coronary sinus; and  
deploying at least a portion of the prosthesis within the coronary sinus to restrain expansion of the mitral annulus.

25 56. A method of reducing mitral annulus diameter as in Claim 55, further comprising the step of percutaneously accessing the venous system prior to the transluminally advancing step.

57. A method of reducing mitral annulus diameter as in Claim 56, wherein the accessing step is accomplished by accessing one of the internal jugular, subclavian and femoral veins.

30 58. A method of reducing mitral annulus diameter as in Claim 55, further comprising the step of advancing the prosthesis from a first configuration to a second configuration to reduce the diameter of the mitral annulus.

59. A method of reducing mitral annulus diameter as in Claim 55, further comprising the step of limiting diastolic expansion of the left ventricle.

60. A method of reducing mitral annulus diameter as in Claim 53, wherein the transluminally advancing step is accomplished using a catheter.

5 61. A method of performing transluminal mitral annuloplasty, comprising:  
providing a catheter, having a proximal end and a distal end and a prosthesis therein;

inserting the catheter into the venous system such that the distal end of the catheter is proximate the coronary sinus;

10 transluminally advancing the prosthesis into the coronary sinus; and  
deploying the prosthesis to influence the size of the mitral valve annulus.

62. A method of performing transluminal mitral annuloplasty as in Claim 61, further comprising the step of causing the prosthesis to exert a compressive force on the adjacent atrial musculature.

15 63. A method of performing transluminal mitral annuloplasty as in Claim 62, wherein the compressive force is generated by a bias in the prosthesis.

64. A method of performing transluminal mitral annuloplasty as in Claim 62, wherein the compressive force is generated by tightening the prosthesis around the mitral valve annulus following the transluminally advancing step.

20 65. A method of performing transluminal mitral annuloplasty as in Claim 64, wherein the tightening step is accomplished by axial movement of a tightening element within the prosthesis.

66. A method of providing a therapeutic compressive force against a tissue structure which is adjacent to a vessel wall, comprising positioning a device in the vessel and exerting a force against the wall of the vessel to exert a force against the tissue structure.

25 67. A method as in Claim 66, wherein the positioning is accomplished percutaneously.

30 68. A method as in Claim 66, wherein the tissue structure comprises the mitral valve annulus.

69. A method as in Claim 66, wherein the tissue structure comprises the left ventricle.

70. A method as in Claim 66, further comprising deploying the device within the vessel.

71. A method as in Claim 66, wherein the vessel comprises a vein.

5 72. A method of performing annuloplasty of the mitral valve comprising positioning a prosthesis in the coronary sinus.

73. A method of limiting diastolic expansion of the left ventricle, comprising positioning a prosthesis in a coronary vein.

74. A method of treating congestive heart failure, comprising:

10 providing an elongate, flexible vascular implant, having a first attachment site spaced axially apart from a second attachment site;

transluminally advancing the first attachment site on the implant through the coronary sinus and coronary venous system to form the implant into an open loop;

reducing the size of the open loop to place tension on the coronary sinus and coronary veins; and

15 attaching the first attachment site to the second attachment site to close the loop and retain tension on the coronary sinus.

75. A method of treating congestive heart failure, comprising:

advancing an implant through an access site and into the coronary sinus;

20 proximally retracting a forming element on the implant while resisting proximal movement of the implant, thereby forming the implant into a desired shape; and

closing the access site, leaving the formed implant within the coronary sinus.

25 76. A method of treating congestive heart failure as in Claim 75, further comprising the step of locking the implant into the desired shape prior to the closing step.

77. A method of treating congestive heart failure as in Claim 75, further comprising: severing at least a portion of the forming element prior to the closing step.

30 78. A method of treating congestive heart failure as in Claim 75, wherein the access site is a percutaneous access site.

79. A method of reducing mitral annulus diameter as in Claim 55, further comprising the step of monitoring the degree of mitral regurgitation.

80. A transluminally implanted device (100) for limiting diastolic expansion of the left ventricle comprising:

an elongate body (102) having a proximal end (104) and a distal end (106);

5 a first attachment site proximate the distal end (106) of the elongate body (102),  
and a second attachment site proximate the proximal end (104) of the elongate body (102); and

means for securing the first attachment site and the second attachment site together.

81. The transluminally implanted device according to claim 80, wherein the  
10 elongate body (102) is flexible and the means for securing is a locking clip (112),  
whereby after the flexible elongate body (102) is looped through the coronary venous  
system (22, 28, 30, 22), the locking clip (112) is cinched onto the proximal end (104)  
and distal end (106) of the flexible elongate body (102) until a requisite amount of  
tension is produced to limit diastolic expansion of the left ventricle.

15 82. A medical device (40) as in claim 41, wherein the elongate body (66) is  
pre-formed into an arcuate shape in the second configuration such that when advanced  
by the delivery member (86) into the coronary sinus (22) it assumes its pre-formed  
arcuate second configuration to apply force to remodel the mitral valve annulus.

20

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/02823

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61F2/02

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 44534 A (UNIV CINCINNATI) 10 September 1999 (1999-09-10) figures 4-13	42
A	page 12, line 1 -page 13, line 23 ---	1,80
X	WO 96 34211 A (BESSELINK PETRUS ANTONIUS) 31 October 1996 (1996-10-31) figure 2A	42
A	page 5, line 18 - line 20 claims 1-17 ----- -/--	1,80

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

18 May 2001

Date of mailing of the international search report

01/06/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040. Tx. 31 651 epo nl.  
Fax: (+31-70) 340-3016

Authorized officer

Mary, C

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/02823

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 00 18320 A (MELVIN DAVID B ;UNIV CINCINNATI (US)) 6 April 2000 (2000-04-06) figures 5,10,16A,17-19	42,80
A	page 12, line 15 -page 15, line 9 page 18, line 14 -page 19, line 17 page 30, line 20 -page 31, line 20	1,81
P,X	US 6 110 100 A (TALPADE DNYANESH) 29 August 2000 (2000-08-29) figures 2-5	42
A	column 3, line 61 -column 5, line 18	1,80

# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 01 02823

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-41,82

A medical device with two configurations (shapes) comprising an elongate body implantable into a vessel to remodel the extravascular surrounding tissue structure.

2. Claim : 42

A medical device with two configurations (shapes) comprising an elongate body implantable into a body space to remodel the extravascular surrounding tissue structure.

3. Claims: 80-81

A transluminally implanted device for limiting diastolic expansion of the left ventricle comprising an elongate body and securing means to the attachment sites.



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/02823

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9944534 A	10-09-1999	US 6190408 B AU 2988499 A EP 1059892 A	20-02-2001 20-09-1999 20-12-2000
WO 9634211 A	31-10-1996	NL 1000225 C AU 5409896 A NL 1000225 A	28-05-1996 18-11-1996 18-07-1995
WO 0018320 A	06-04-2000	US 6221103 B AU 1199800 A	24-04-2001 17-04-2000
US 6110100 A	29-08-2000	EP 1073488 A WO 9953977 A	07-02-2001 28-10-1999

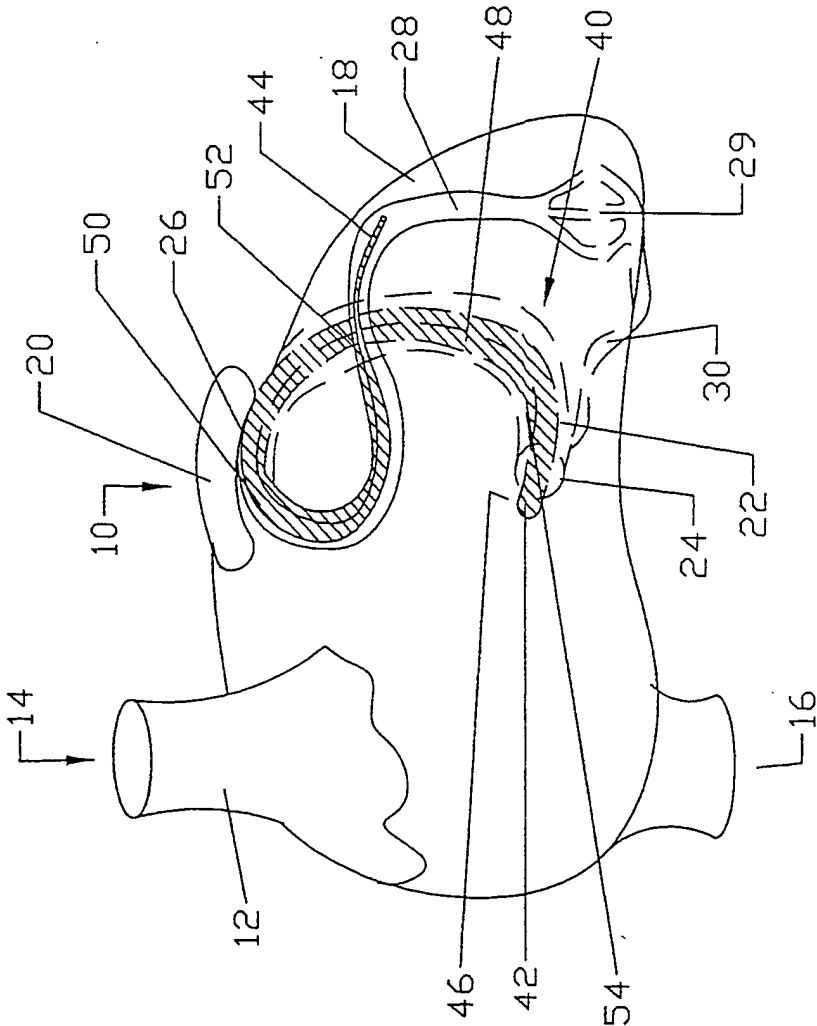


FIGURE 1

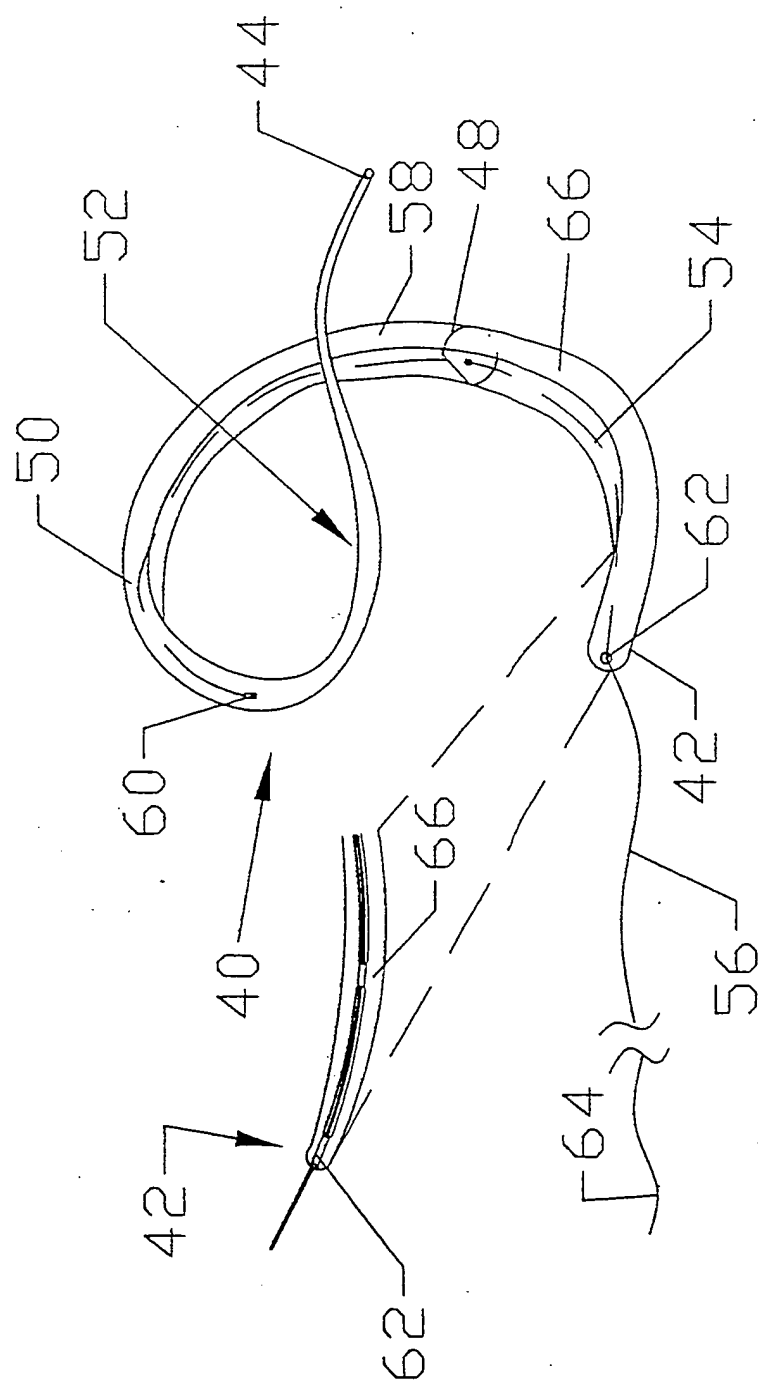


FIGURE 2

FIGURE 3

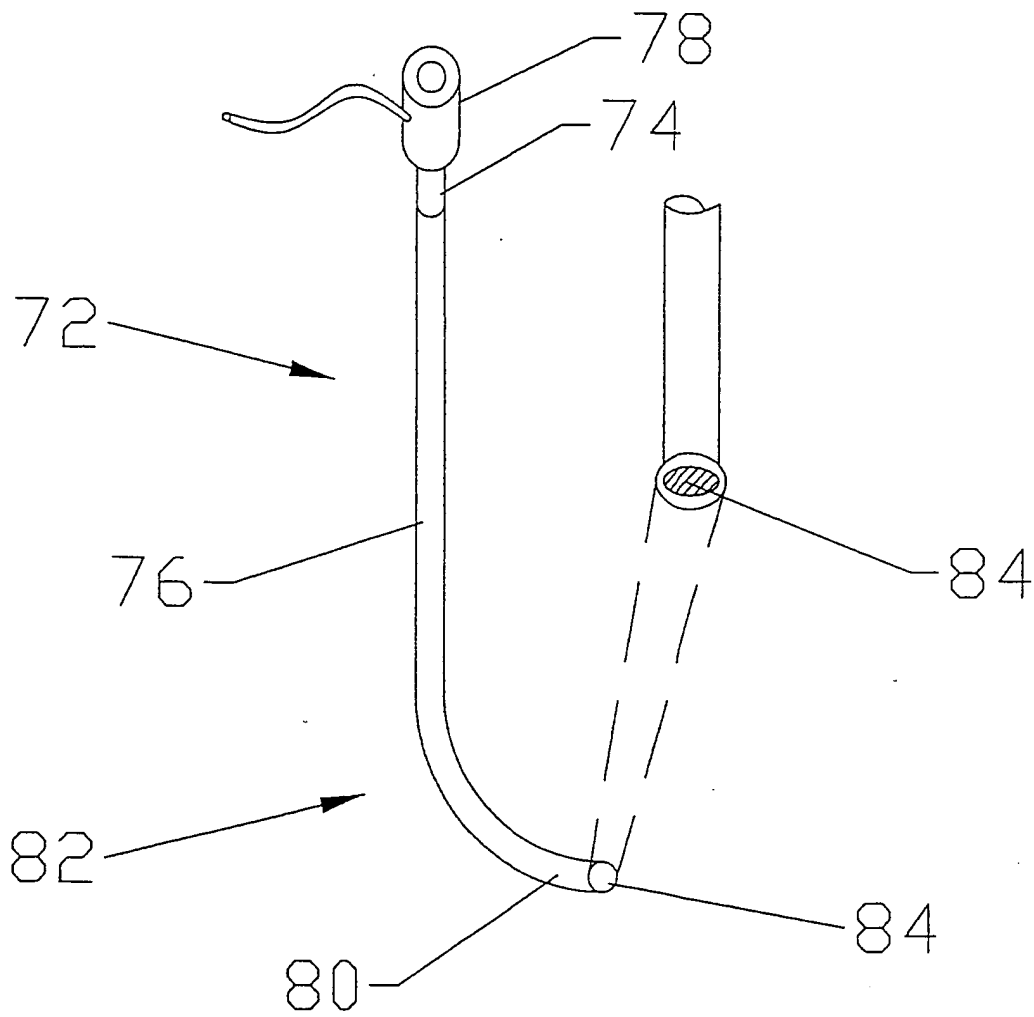


FIGURE 4

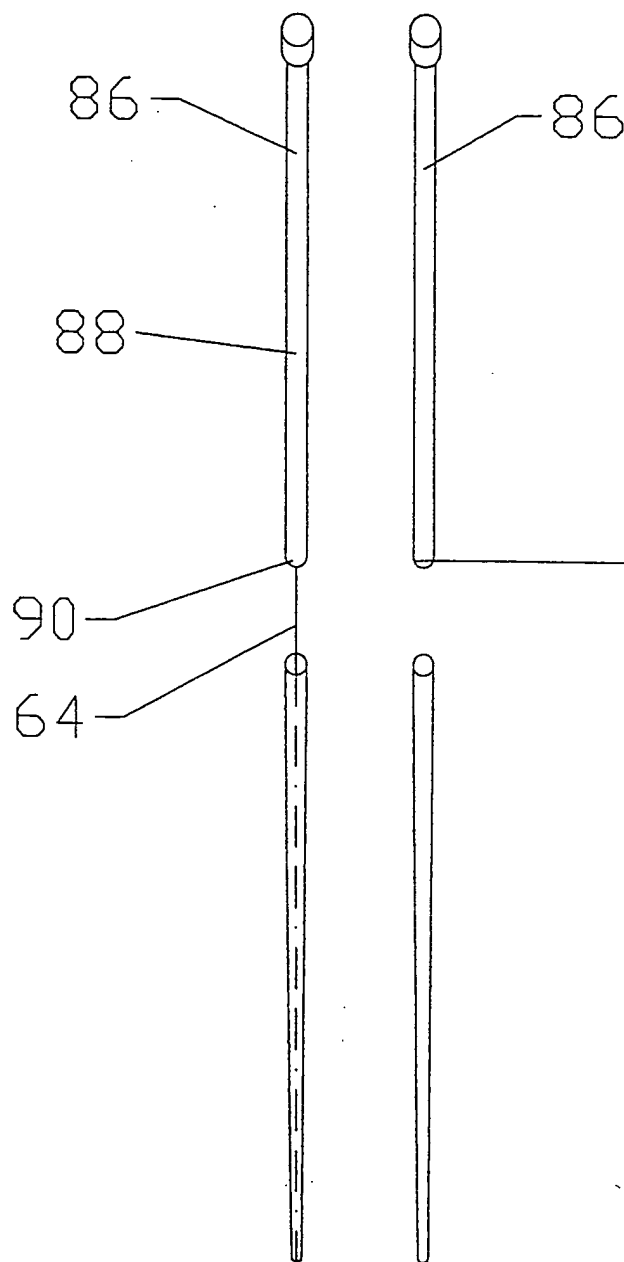
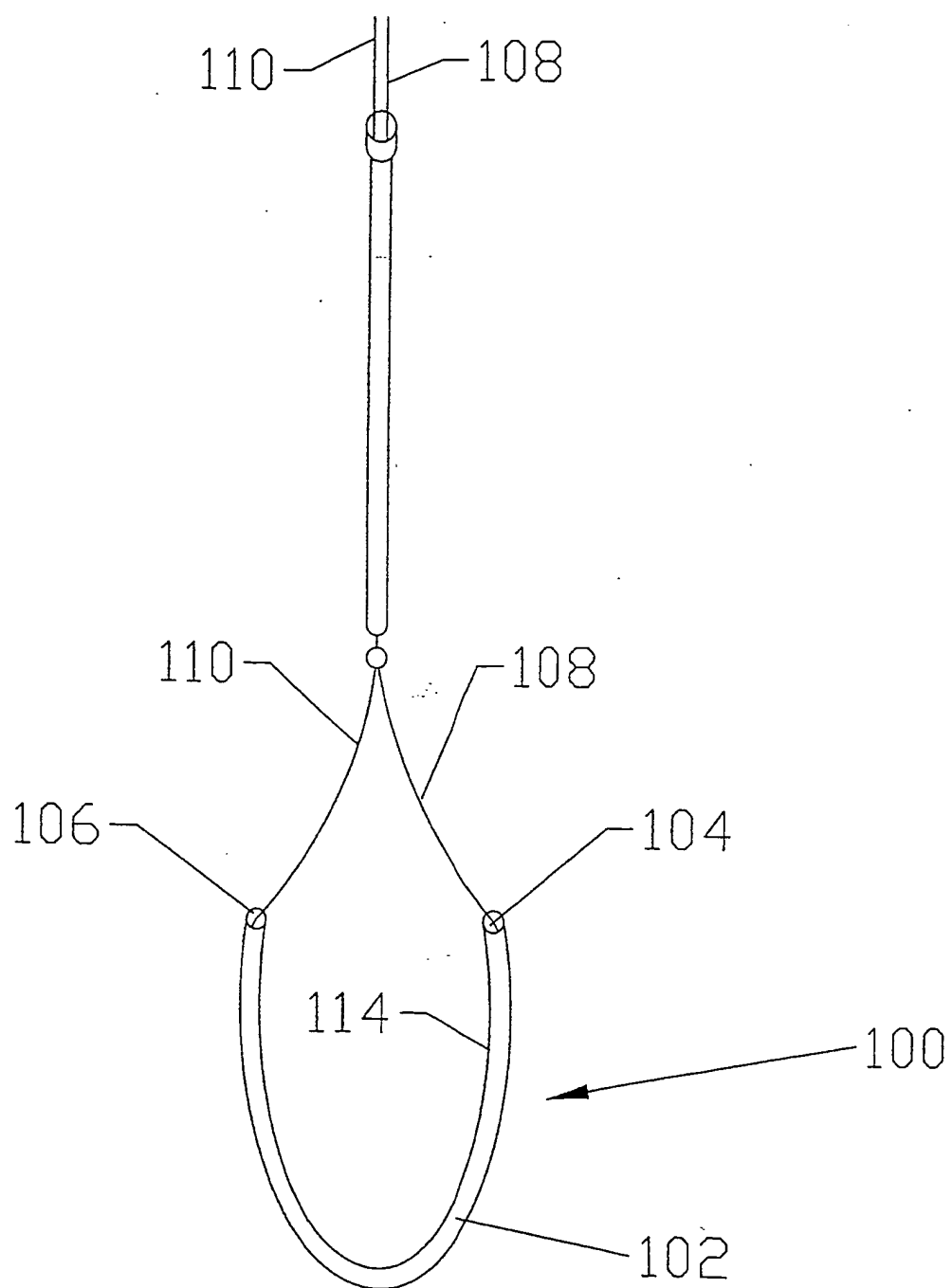


FIGURE 5



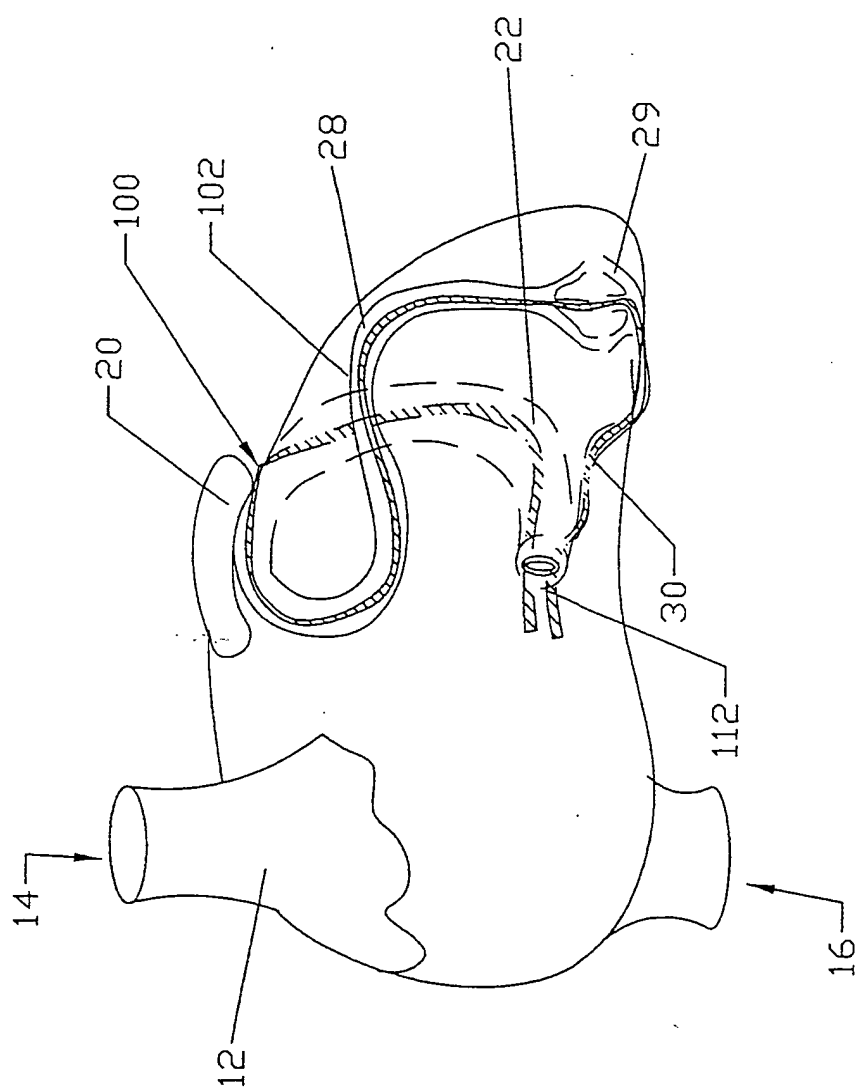


FIGURE 6

FIGURE 7

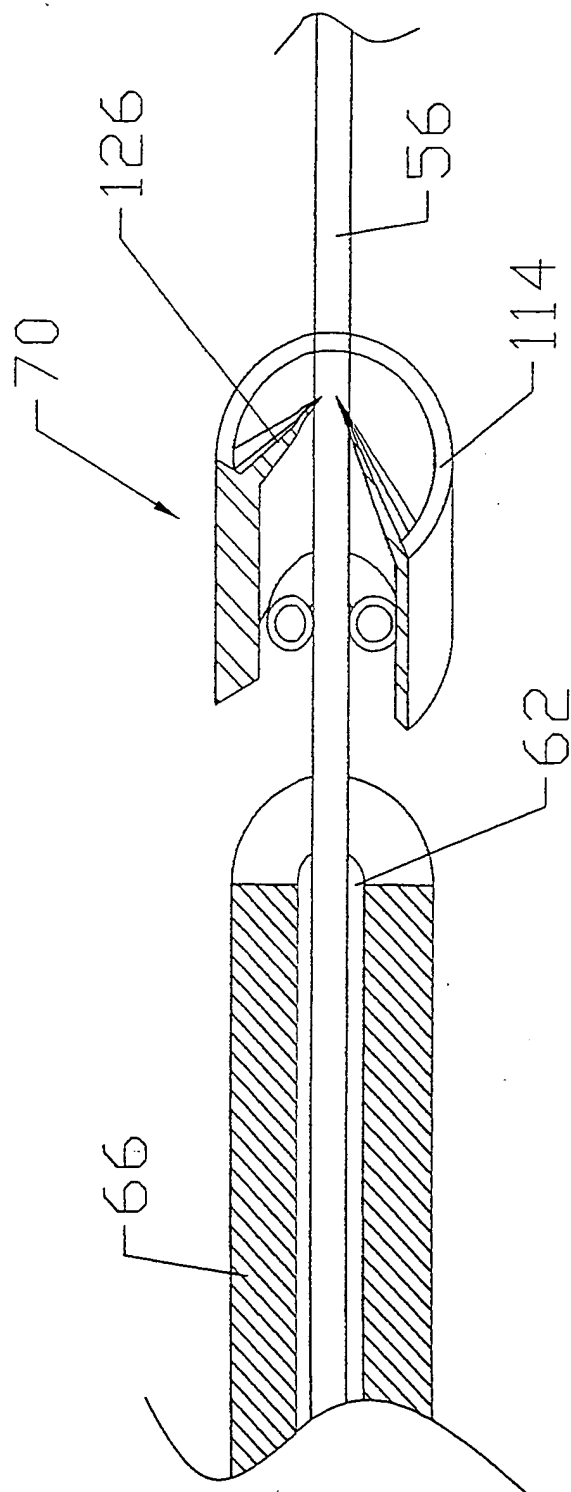
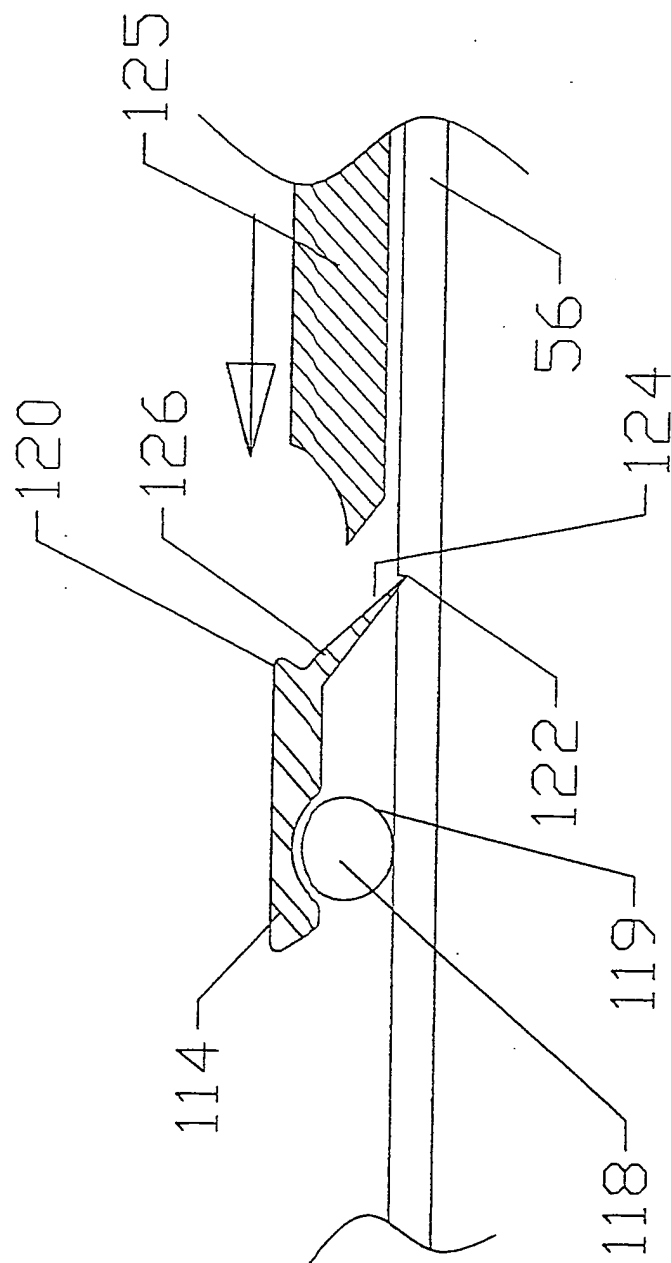




FIGURE 8





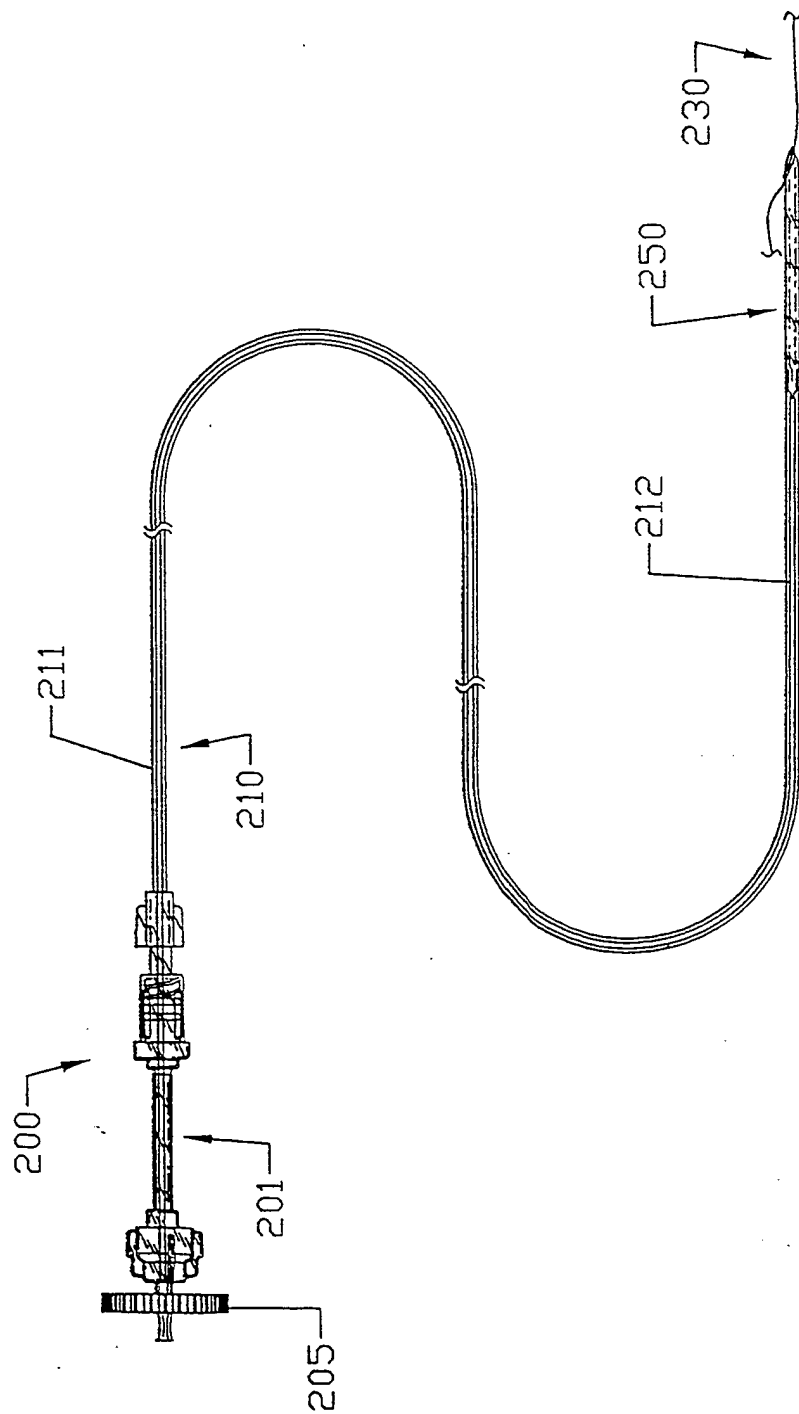


FIG. 10

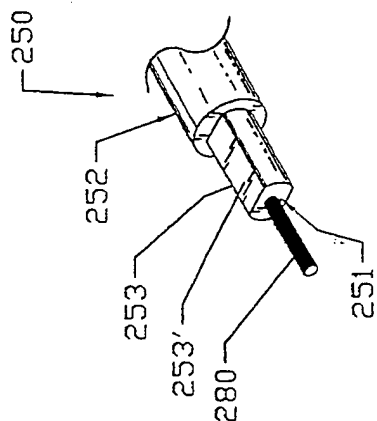


FIG. 12A

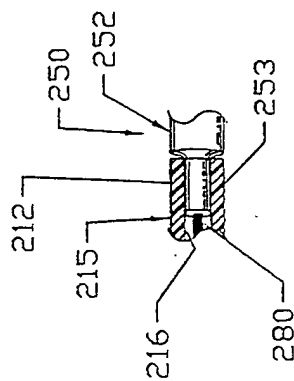


FIG. 12B

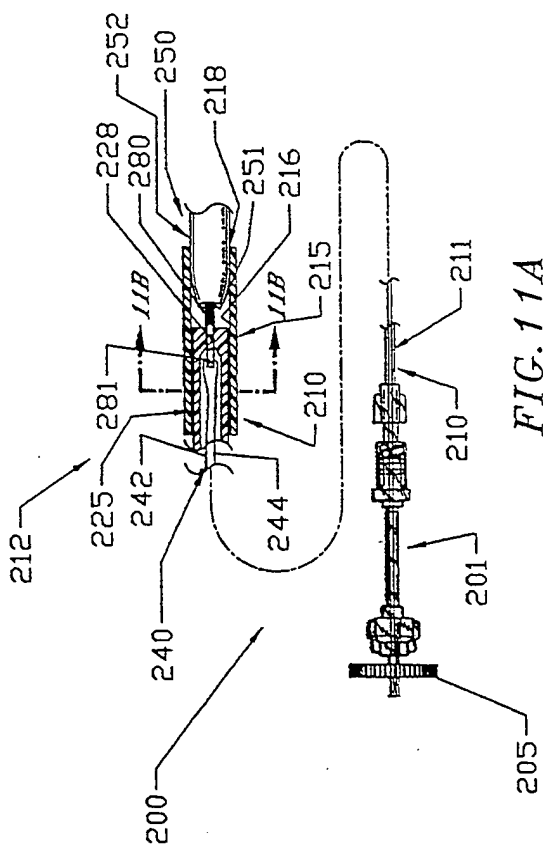


FIG. 11A

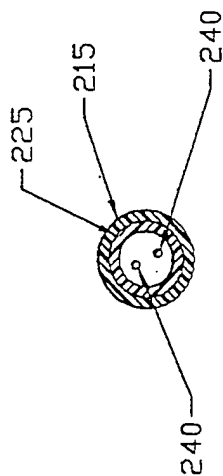


FIG. 11B

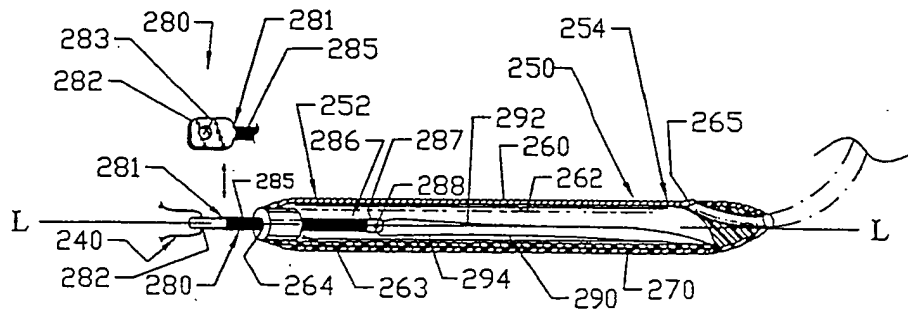


FIG. 13A

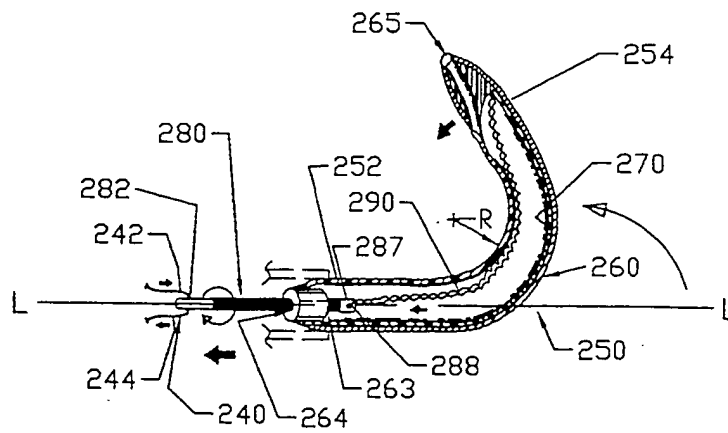


FIG. 13B